

## Healthcare Transformation Collaboratives Cover Sheet

**1. Collaboration Name:**

South Side Diabetes Prevention Collaborative

**2. Name of Lead Entity:**

First Mile Care

**3. List All Collaboration Members:**

First Mile Care  
Christian Community Health Center  
Beloved Family Community Wellness Center  
Chicago Family Health Center  
Family Christian Health Center TCA Health, Inc.

**4. Proposed Coverage Area:**

The zip codes are: 60406, 60409, 60411, 60419, 60426, 60428, 60438, 60455, 60469, 60472, 60473, 60617, 60619, 60620, 60621, 60628, 60629, 60632, 60633, 60636, 60637, 60643, 60649, 60803, 60827.

**5. Area of Focus:**

Diabetes Prevention

**6. Total Budget Requested:**

\$7,417,632



## **South Side Diabetes Prevention Collaborative**

Prepared by First Mile Care, Inc  
for Department of Healthcare and Family Services Healthcare Transformation Collaboratives

**1. Participating Entities**

**Contact Information for Collaborating Entities**

1. What is the name of the lead entity of your collaborative?

South Side Diabetes Prevention Collaborative

2. Please provide primary contact information, secondary contact information, and of each entity in your collaborative.

Please list the lead entity in the top row.

EntityName	Primary Contact	Position	OfficePhone	Secondary Contact	Secondary Contact Position
First Mile Care	Karl Ronn	CEO	(650) 656-9856	Sehoon Kwak	Vice President
Christian Community Health Center	Kenneth Burnett	CEO	(773) 233-4100	Lee Madigan	Senior Director of Strategic Development and Business Operations
Beloved Family Community Wellness Center	Margie Johnson	Executive Director	(773) 651-3629	Sandra I. Flores	Director of Development and Communications
Chicago Family Health Center	Barrett Hatches	President/CEO	(773) 364-2201	Sandra I. Flores	Director of Development and Communications
Family Christian Health Center	Lisa Green, MD	CEO/Co-Founder	(708) 596-5177	Sandra I. Flores	Director of Development and Communications
TCA Health, Inc.	Veronica Clarke	President and CEO	(773) 995-6300	Lee Madigan	Senior Director of Strategic Development and Business Operations

3. Please confirm that you have entered the required information for each entity in the table above including secondary contact information and Tax ID #.

I confirm

4. Please upload the most recent IRS Form 990 (including Schedule H, if applicable) for all participants in the collaboration. (Done – redacted for this document)

- Are there any primary or preventative care providers in your collaborative?  
 Yes

1A. Please enter the names of entities that provide primary or preventative care in your collaborative.

First Mile Care  
Christian Community Health Center  
Beloved Family Community Wellness Center  
Chicago Family Health Center  
Family Christian Health Center  
TCA Health, Inc.

1. Are there any specialty care providers in your collaborative?  
 No

2. Are there any hospital services providers in your collaborative?  
 No

3. Are there any mental health providers in your collaborative?  
 Yes

4A. Please enter the names of entities that provide mental health services in your collaborative.

Beloved Family Community Wellness Center  
Chicago Family Health Center  
TCA Health, Inc.

4. Are there any substance use disorder services providers in your collaborative?  
 Yes

5A. Please enter the names of entities that provide substance abuse disorder services in your

collaborative. **Christian Community Health Center**  
Beloved Family Community Wellness Center  
Chicago Family Health Center

5. Are there any social determinants of health services providers in your collaborative?  
 Yes

6A. Please enter the names of entities that provide social determinants of health services in your collaborative.

First Mile Care  
Christian Community Health Center

6A. (Cont)

Chicago Family Health Center

Family Christian Health Center

TCA Health, Inc.

7. Are there any safety net or critical access hospitals in your collaborative?

No

8. Are there any entities in your collaborative that are either certified by the Illinois Business Enterprise Program (BEP) or not-for-profit entities that that are majorly controlled and managed by minorities?

Yes

8A. Please list the names of the entities in your collaborative that are either certified by the Illinois Business Enterprise Program (BEP) or not-for-profit entities that that are majorly controlled and managed by minorities.

Christian Community Health Center

Beloved Family Community Wellness Center Chicago Family Health Center

Family Christian Health Center TCA Health, Inc.

9. Please list the Medicaid-eligible billers (firms that can bill Medicaid for services) in your collaborative, and the Medicaid ID for each.

Beloved Community Family Wellness

- Medicaid ID: 043828358001 for 6821 S Halsted St, Chicago, IL 60621 location
- Medicaid ID: 043828358003 for 3518 W 139th St, Robbins, IL 60472 location

Family Christian Health

- Medicaid ID: 364161801001

Christian Community Health

- Medicaid ID: 363799834005 for 9718 S. Halsted Chicago, IL 60628
- Medicaid ID: 363799834006 for 364 Torrence Avenue Calumet City, IL 60409
- Medicaid ID: 363799834008 for 901 E. Sibley Blvd South Holland, IL 60473

Chicago Family Health

- Medicaid ID: 362893854007

TCA Health

- Medicaid ID: 363828320001

10. Below are high-level descriptions of project types that appeared in the Transformation funding statute. Check any that apply to your project; if none apply, please provide a brief description of what kind of entities comprise your collaboration. (This question is informational only and will not affect your eligibility).

- Safety Net Hospital Partnerships to Address Health Disparities
- Safety Net plus Larger Hospital Partnerships to Increase Specialty Care
- Hospital plus Other Provider Partnerships in Distressed Areas to Address Health Disparities (led By Critical Area Hospitals, Safety Net Hospitals or other hospitals in distressed communities)
- Critical Access Hospital Partnerships (anchored by Critical Area Hospitals, or with Critical Area Hospitals as significant partners) Cross-Provider Care Partnerships
- Led By Minority Providers, Vendors, or Not-For-Profit Organizations Workforce Development and Diversity Inclusion Collaborations
- Other

## 2. Brief Project Description

1. Provide an official name for your collaboration.

South Side Diabetes Prevention Collaborative (SSDPC)

2. Provide a one to two sentence summary of your collaboration's overall goals.

The SSDPC will work to prevent diabetes among 100,000 Black, Latinx, and other patients in the South Side community of Beloved Community Family Wellness Center, Chicago Family Health Center, Christian Community Health Center, Family Christian Health Center, and TCA Health, Inc., all Chicago-based Federally Qualified Health Centers (FQHCs). Building on a successful collaboration between these FQHCs and other community partners already working together in the Southside Healthy Community Model, First Mile Care will offer a Centers for Disease Control (CDC) and Center for Medicare and Medicaid Services (CMS)-recognized Diabetes Prevention Program (DPP) to all their patients with prediabetes in a way that will result in a programmatically and economically sustainable model for long-term effective community-based diabetes prevention.

## Detailed Project Description

Provide your narrative here:

### 1. Our Service Area

The SSDPC service area will be made up of the contiguous zip code districts (represented in gray in the map below of Cook County) in which the 5 FQHC's have clinics (marked with crossed red circles). The specific service area zip codes are: 60406, 60409, 60411, 60419, 60426, 60428, 60438, 60455, 60469, 60472, 60473, 60617, 60619, 60620, 60621, 60628, 60629, 60632, 60633, 60636, 60637, 60643, 60649, 60803, 60827. Zip codes in the county that are cross-hatched have large Latinx populations, some of which are located in our service area.

### 2. Health Care Challenges

Throughout America as a whole, one in three adults have prediabetes, a condition of elevated blood sugar that is not yet at the level of diabetes but left untreated risks turning into full-blown diabetes. Underserved communities have even higher risks for a number of reasons, including social determinants of health discussed in more detail below in Form 9. We estimate the population we are serving in this collaborative has about 40% of adults with prediabetes. As elsewhere in America, most of these people will be unaware of their risk because it is a silent condition without symptoms and can only be diagnosed through blood tests. The collaborating FQHC's have a patient population of 100,000 people, about 90,000 of whom are adults. We estimate about 54,000 have prediabetes and therefore are candidates for our program.

Key to diabetes prevention are weight loss and increased physical exercise. Both are problematic for the individuals in our target population, living in what amounts to "food deserts" with few available sources of healthy lower caloric foods and often in neighborhoods that are high crime and few recreational facilities. Weight loss and physical exercise can be challenging for all adults in need of them, but are especially hard for lower income individuals like those in our service area. Notably, the average income for our target area is \$42,174 versus Cook County's average of \$69,429 (2019 ACS Estimates).

### 3. Project Goals

Our project benefits from the fact that Type 2 (Adult Onset) Diabetes is a preventable condition, and we know how to prevent it. Preventing progression to it not only saves patients a great deal of misfortune in terms of difficult to manage disease treatment and very debilitating, all-to-common side effects but also a great deal of expense: an estimated \$16,000 a year, a cost shared with insurance providers, including public ones like Medicare and Medicaid. So our overall goal is to prevent progression from prediabetes to full blown diabetes for as many individuals in our service area as possible. Fortunately, we know this is entirely possible. The CDC has endorsed a diabetes prevention program, which our program replicates, that has been shown by research published in the *NewEngland Journal of Medicine* in 2002 to reduce the risk of type 2 diabetes by 58% overall and 71% for people over 60 (NEJM reference). See the detailed discussion of our DPP's evidential base below in Form 6.

To quantify this goal, our collaborative will deliver the CDC's DPP program to 5,000 people over 5 years. To set this service goal in perspective, it is worth noting that the CDC reported that as of April 2019 only 4,146 people in the entire State of Illinois had benefited from any diabetes prevention program since the agency endorsed it as a best practice for prevention. Thus, our goal of serving 5,000 people would exceed diabetes prevention's state-wide success to date, and with one of the state's most economically challenged populations.

Since our DPP curriculum, which stresses activity, diet, and stress management skills, has also been shown to reduce immediate health costs by an average of \$770 per person in other non-diabetes related health issues. We will also measure the additional health care savings for the people we serve in this collaboration. Capturing the short-term health care savings on top of the long-term benefits of preventing diabetes will enable our DPP program to show how it can sustainably pay for itself even in the short-term for patients and the State.

### 3. Strategy

Our program strategy includes numerous new interventions and delivery redesigns (see below) while remaining true to the CDC's specifications for diabetes prevention programs. As per those specifications, our program offers a community-based in preference to a medical delivery model in which coaches deliver neighborhood culturally astute guidance, support, and reinforcement for weight loss, increased exercise, and stress reduction in time convenient and readily accessible community settings. Given that DPP in accordance with CDC specifications requires a substantial time commitment of 22 one-hour classes over a year, our primary recruitment target will be people who are over 45 who have been shown in previous First Mile Care implementations to have higher probabilities of taking the program for various reasons. They are, for instance, typically past child rearing age and freer to make the time commitment and often have become more sensitive to the importance of maintaining health. Of the 54,000 individuals in our service area whom we estimate have prediabetes, about 36,000 are in this age cohort. Again, based on previous program implementation experience, we expect 15% of this group will enroll and 8.3% will attend the program. This initial target group nonetheless represents about 3,600 people or 72% of our 5,000-person goal. We will however continue to conduct outreach throughout all five program years.

This collaborative builds on the successes of the 5 FQHC's who are serving the underserved populations in the targeted zip codes on the South Side of Chicago. Program activities will include the following:

- Building the capability to offer local DPP classes at the zip code level for the entire service area
- Hiring and training part-time local coaches (13 deployable at any given time) to lead the classes
- Hiring and training staff to educate and perform outreach and enrollment of participants, educating them about their pre-diabetes risk
- Identifying local available rented locations (e.g. churches) for program delivery
- Developing curricula for the classes
- Providing in-person coaching within 10 minutes of all patients' homes and at many convenient times. (During covid the cohorts will meet via Zoom but still recruit at a zip code level.)
- Offering support for participants to maximize retention (e.g., make-up classes, IT support, reminders)
- Offering FQHC's a program support team and providing financial support for any patient requested A1c testing
- Reporting patient outcomes to the FQHC's

Participants will qualify for the DPP program based on CDC criteria for identifying risk for diabetes. Key criteria include: Blood tests with A1c >5.7 and <6.2, Fasting Glucose >100mg/ml and <125 mg/ml or a score of > 5 on the CDC's prediabetes test. Previous program implementation experience has shown that indicative blood test results

are usually the one thing that motivates participants to commit to action on the principle of *Your Blood Never Lies* (see James LaValle's book of that title, aptly subtitled *What Your Blood Test Reveals About Your Health & What You Can Do About It* [Garden City Park, New York, 2013]). So we will encourage Hemoglobin A1c testing and have allocated funds to allow the FQHC's to do three tests per participant: a test prior to enrollment if not already available, a test after eight classes, and a test after one year. This is expected to provide considerable encouragement to participants as well as to allow us to better measure success or understand how to improve the collaboration during the 5-year period of the grant.

This 12-month program of 22 classes for participants is expected to be delivered in person by First Mile Care on behalf of the five FQHCs in our collaborative. First Mile Care has had successful experience with virtual delivery during the COVID pandemic that could be deployed if future emergency conditions require. First Mile Care is an experienced Diabetes Prevention Program provider, recognized by the CDC for meeting its program requirements, qualified as Medicare provider, and is also a state Medicaid DPP provider in Illinois. It has successfully implemented equivalent DPPs in Detroit and Ann Arbor, Michigan, Houston, Texas, and San Francisco. First Mile Care was founded by the American Medical Association's (AMA) Health 2047 new venture firm. The company was founded after working with the AMA and the CDC to understand and address the issues that had prevented rapid scaling of the DPP effort. This collaborative's plans directly address those barriers.

#### 4. Capital Improvements

There is no need for capital improvements—which are often very costly—in our program design. While there is no doubt that some very expensive neighborhood improvements like a new low-cost comprehensive grocery store or an affordable gym or other location(s) for physical exercise would be boons to our service population with respect to diabetes prevention, our model seeks to secure many of the same benefits at much lower cost while assuring sustainability independent of the business fortunes of new, capital-intensive investments in the community that often turn out not to be long-term successful as economic enterprises.

#### 5. New Interventions and Delivery Redesigns

*Neighbors Helping Neighbors at a Zip Code Level.* Retention is a key factor in our DPP's success since habit change is iterative. Participants must make a specific weekly plan, try it, succeed or fail, and if necessary, learn to make new plans. The learning occurs under the guidance of a trained coach from their own community who facilitates sessions with cohorts of approximately 10 people. Whenever possible, these 10 participants are neighbors. This social proximity facilitates participants' mutual learning process and encourages them to embrace sometimes difficult lifestyle changes even when the local neighborhood has structural problems that make it hard to live a healthy life.

These are the most important factors in our hyper-local zip code level program design:

- Neighbors serve as cohort members, engaging in action planning that reflects what is possible now as worthwhile prevention activities within 10 minutes of their homes and each of them observing what is working for the others in their group that can be adopted in his/her personal action plan.
- Trained local coaches are local people, making it easy for each participant to “learn from someone like me.”
- Meetings scheduled close by and at times agreed to by the cohort, not at pre-arranged times for the convenience of program administrators or staff.
- Participant bonding is promoted in various ways: finding a partner with whom to go for regular walks outside of the classes or to discuss dietary strategies and other concerns. This promotes networks of neighbors and enduring local support for success.
- Strengthening of connections to participants' health care providers, starting with a physician's personal invitation to participate in the program.
- A focus on a limited but still effective, worthwhile, and more easily maintained weight loss that is different from asking participants to embark upon “another impossible to maintain diet.” This dispels myths (“no diet ever works for me”) and builds confidence in being able to attain what is necessary for good health.
- Money plowed back into the community: salaries for local recruiting and coaching staff; rent payments to local institutions for hosting sites; expenditures by participants for healthy foods provided by neighborhood vendors. Our coaches will be paid about \$565,000 and we will rent space in the community amounting to about \$620,000.
- Additionally, we will create 5 full time jobs for local members of the community to lead the program for a total of \$1,972,000.

- We also will be utilizing the services of BEP companies to serve the community including: Capgenus for management of the program, Around the Clock Transportation for assisting participants with attending meetings, and RLM Media for Diabetes Prevention awareness.

*Creating Supply and Demand Simultaneously.* DPP is designed for 10 person cohorts who meet with a trained coach for the 22 sessions over the course of a year. Participants must commit to a year-long schedule of one-hour meetings. Developing means to maximize participant retention is a key need to address prior to enrolling people. This means two things need to happen: designing for high commitment to try the program (“generating strong demand”) and scheduling enough nearby classes to enable convenient attendance (“generating the needed supply”). Historically, not all prevention initiatives have paid sufficient attention to both of these needs but doing so has been a major factor in First Mile Care’s previous DPP implementations in similar communities of acute need around the country.

*Creating Demand.* The program relies upon and secures recommendations (written, oral, or both) from each potential participants’ trusted provider of health care, be that an individual primary care physician or other health care provider in a familiar FQHC. This creates a high intention to engage with the program, more than say, a program leaflet given to a prospect, no matter how well it is prepared. By contrast, failed prevention models relied on by health care organizations is to give eligible patients referrals to a prevention program as they are identified in office visits. In addition to having a poor response rate generally (it is well known that even physicians’ pharmaceutical prescriptions are often not filled), this wouldn’t work for our model because 10 patients at a time would need to agree to a time and place, both most likely set by us, for a class to have sufficient enrollment for it to happen. While referred patients wait for the class to fill, they lose interest – the window of action has passed.

A key part of demand planning will be to build, with close cooperation with the FQHCs, a registry of all their patients who have prediabetes. The registry will include home address locations that will allow the collaborative to predict where the classes will have to be for participants’ convenience and how many people will be in them prior to initiating recruitment.

*Creating Supply.* With knowledge gained from the demand plan we can commence generating the supply at the zip code level (supply planning). This means hiring the coaches from those particular neighborhoods, training them on DPP and our systems, and finding and contracting locations for each zip code to be served. We know from experience that we will need to offer classes at about 5 different times to meet people’s schedules for each zip code. We also know that since people can only commit to start classes at certain times of the year, we develop schedules that respect school schedules and holidays.

The program will work by estimating the supply that is needed at a zip code level for each month of the 5-year period. Then we will activate the demand drawing appropriately on the registry of patients who have prediabetes. We will make a specific offer for classes we know can occur in their neighborhoods and knowing we have coaches who will be available for these specific times.

*Recruitment.* With supply and demand plans in hand we will be able to start the recruiting process. Recruitment will focus broadly on three populations of the FQHC’s patients and in this order of sequence:

- Patients who have been seen in the last 12 months and have blood tests indicating prediabetes.
- People who have been seen in the last 12 months but don’t have a prediabetes determination.
- People who have not been seen in more than 12 months.

Our initial outreach will be to the first group that has had a determinative blood test. The FQHC’s are working on their programs for the latter two groups to complete their overall health care screening and to re-engage the people they haven’t seen in a year or more. Given the incidence of prediabetes, it is likely that many would benefit from the program, but we will recruit from these groups once the FQHC’s instruct us that they have reestablished the relationships with these people.

As a result, we projected an actual enrollment of 5,125 that increases over the five years:  
Year 1 – 550; Year 2 – 675; Year 3 – 900; Year 4 – 1200; Year 5 – 1,800

This amounts to offering about 15,000 DPP sessions over the 5 years.

First Mile Care’s previous enrollment experience suggests that about 15% of people offered classes will enroll and project 8.3% will actually attend. The drop off is expected as people reconsider their ability to commit to a year-long

series of classes. But the people who express interest but don't show up will be offered classes again in the following years as they likely were just not ready when they received the first offering.

Using Business Associates Agreements that will allow sharing of Personal Health Information (PHI), First Mile Care will manage all outreach to patients on behalf of the entire collaborative. We will do this with a combination of mailed letters and phone calls. The goal is to answer potential participants' questions about prediabetes and the program and then work with each of them to agree to times and places for the meetings that meet their schedules. The FQHCs know that many people in their service populations are unstable in residence, even in the course of a single program year, so we will be setting up meetings in a wide range of zip codes to address this problem of transient residence. We also plan to work with RLM Media and a local BEP media agency to develop the appropriate awareness campaigns in support of the overall effort.

We will be recruiting about 5 cohorts of 10 individuals per zip code at a time in order to offer a range of times. With the 8.3% yield rate this means handling about 500 invitations at a time in a single zip code.

Outreach will be conducted by Participation Engagement Associates (PEAs) whom we will hire locally. Outreach will be attempted up to 7 tries with each candidate using a combination of mail and phone calls. Experience has shown that multiple outreaches, using a variety of formats, are necessary so the potential recruit can understand the program requirements and be prepared to commit. Over the course of the five-year program, we project a need for approximately 375,000 interactions that are educational or scheduling-related in nature. This education and outreach are a major cost of about \$1,000,000 over the life of the program but all this money will be spent in the community.

*Program Management.* The program will hire 3 management positions initially to manage the program locally and this will grow to 5 full time people as the participant volume expands. These people will work across the 5 FQHCs to address any program support needs. The initial 3 positions will be the Coaching, Outreach, and Administration Managers. We have budgeted \$100,000/person including benefits for these jobs. We will leverage the existing First Mile Care systems and corporate support for this program implementation without charge. The FQHCs will also have important project management responsibilities. To assure that management, reporting, and evaluation responsibilities are not additional burdens to the FQHCs, we provide a total of \$300,000 per FQHC for the 5-year period. In addition, the FQHCs will play crucial role in showing how the program sustainably reduce health care costs. The collaborators will collect short-term health care cost benefits from using participants and non-participants. Over a three-year period, they will compare the actual health care system utilization to show the short-term benefit to preventative activity to all aspects of the patients' health. These benefits are above and beyond the proven long-term benefits of DPP.

All data will be collected in a HIPAA compliant system. No data will be used for any other purpose than agreed by the FQHC's. Anonymized results will be reported to the CDC and CMS for maintaining the program's recognition status. In Year 4 we propose moving toward sustainability by recovering Medicare, Medicaid and any other insurance as permitted through their billing codes. A detailed discussion of our sustainability plan will be found below in Form 16.

Summary: Type 2 diabetes is preventable. The program for diabetes prevention is proven to reduce the risk by up to 70% for people over 60 and has additional benefits in lowering overall health care costs. This collaboration builds on the success of the 5 FQHC's who are already improving the health of the South Side population. This adds a critical diabetes prevention program. Diabetes costs \$16,000/ per year for life to manage. Our goal is to stop that from ever happening. We also foresee quantifying the short-term health care savings that will essentially pay for the program in the short-term while creating the longer-term reduction in diabetes. This will improve the life of the people we touch and lower the costs of healthcare in the state of Illinois. We expect this project will enhance the understanding and importance of prevention for many chronic diseases. For instance, chronic kidney disease — highly associated with diabetes — is growing rapidly with new dialysis clinics being established every year, after year disproportionately in the South Side neighborhoods. By preventing diabetes we can also help reverse this trend and the \$30-90,000/year per person costs of hemodialysis.

## 6. Need for Each Significant Item in Our Budget

The principal cost items in our budget are:

### **Class Delivery Costs – \$1,440,000**

We will be delivering 15,000 DPP classes. This includes coach salaries, rental of space for meetings, training of the coaches and the materials used in classes.

### **Education and Outreach – \$1,270,000**

The classes will be offered to all the people who have prediabetes. This requires multiple outreach letters, calls and discussions to educate more than 50,000 people on prediabetes and the DPP classes and then enroll them in the classes that meet their schedules.

### **Local Management – \$1,970,000**

The local team leadership includes 5 managers who will be hired from and live in the South Side to support the DPP program and work directly with the FQHC collaborative partners. This local team will execute the program, learn what is needed to improve the program to reflect the needs of the community and implement those changes to increase the success of the participants.

### **FQHC Disease Prevention Capability – \$1,500,000**

Each of the five FQHCs will have an annual budget to build the capability to deliver preventative care and ensure that the reporting, management, and other needs of the program do not interfere with their other health priorities for their patients. Additionally, we will track the overall health of the patients who took the DPP program versus a control group who chose not to participate. These health economics will help show the benefits of DPP pay out in the short-term as well as the longer-term diabetes prevention.

### **Health Measurement – \$450,000**

Hemoglobin A1c (HgA1c) tests is the gold standard for assessing blood sugar related to diabetes. To measure the effectiveness of the program in preventing diabetes we will ask and pay for participants to take HgA1c tests prior to enrolling, once during the classes, and again after 12 months.

## 3. Governance Structure

### Structure and Processes

1. Please describe in detail the governance structure of your collaboration and explain how authority and responsibility will be distributed and shared. How will policies be formulated and priorities set?

Should it be the recipient of an HTC award, the members of the South Side Diabetes Prevention Collaborative (SSDPC) will meet as soon as practical upon announcement of the award to develop a memorandum of understanding (MOU), a binding contractual agreement, that will set out the respective responsibilities of each member of the collaboration.

The MOU will address the following HTC required elements:

1. General Provisions

- Authority and responsibility of participants (see also below)
- Statement that participants pledge to adhere to collaborative policies
- Statement regarding participants responsibility and accountability for achieving desired outcomes
- Statement of participant's agreement to honest dealing, acting prudently, ethically, and in good faith regarding the collaborative

2. Scope of Participation for Each Entity
  - Responsibilities
  - Staffing commitments
  - Title and job description of employees assigned to collaborative
  - Staff weekly hourly commitment
  - In kind resource commitment (if any)
  - Evidence of authorization from each participating entity's governing authority
  - Requirements that each participating entity has policies regarding each of the following: Non-discrimination, Sexual harassment, Diversity, Training, Ethics, and Record Keeping and Reporting Requirements Policies
  - Duration of the agreement
3. Financial Management Arrangements
  - Identification of First Mile Care as the fiscal agent
  - Internal fiscal integrity measures and safeguards to ensure that the funds are distributed and used for the collaborative's proposed intended purpose.
  - Fund Distribution Policy and Procedures
  - Statement of agreement with FQHCs who receive directed payments to distribute them on a timely basis to the fiscal agent of the collaborative

Regarding the aforementioned authority and responsibilities of the participants, our informal understanding, to be finalized post-award and formalized in the MOU, is that these will be as follows:

1. The FQHCs will work with First Mile Care to identify patients in the three categories appropriate as referral candidates to First Mile Care's DPP.
2. First Mile Care will be responsible for recruitment and engagement of candidates so referred to DPP.
3. First Mile Care will pay for A1c testing, the "gold standard" for accurate identification of pre-diabetic individuals, for those referral candidates who have not previously been so tested.
4. First Mile Care will utilize HTC grant funds to pay for all costs of DPP for referred participants and—whenever possible—insurance providers including Medicaid. The undersigned FQHCs will not be obligated for any of these costs.
5. First Mile Care will share HIPPA-compliant testing results and program outcomes with the referring FQHCs at no cost to them.
6. The undersigned FQHCs will endeavor to maintain patient referral streams to First Mile Care's DPP during the five year life of the grant and share relevant HIPPA compliant patient data important for the program's success and evaluation according to business associate agreements drawn up for this purpose.
7. The collaborators will discuss in detail how the 3 management positions will work with the FQHC staff who support the diabetes prevention initiatives that are funded inside each of the FQHCs.
8. The FQHCs and First Mile Care will participate in a coalition governance structure—to be finalized post-award—for the purposes of continuous quality improvement, responsiveness to patient feedback, and exploration of sustainability options for DPP in the post-grant period.

It is understood by all of us that the MOU will need to be finalized based on the contract DHFS will issue to the SSDPC in the event of an award. After mutually agreeable necessary changes, we will draw up a Business Associates Agreement, a binding contract, to assure all members of the collaboration understand and fulfill their obligations and responsibilities.

On an agreed upon temporal basis, not less than quarterly, minimally the First Mile Care SSDPC Project Leader, the First Mile Care Regional Coordinator, the Coaching, Outreach and Administration Managers FQHC-embedded Project Coordinators, and the Chief Executive Officers of the collaboration's FQHCs or their designees will meet to discuss continuous program quality improvement, how to assess and respond to patient feedback, and how to promote program sustainability post award. The First Mile Care SSDPC Project Leader or his designee will chair the meeting.

## Accountability

2. How will collaborating entities be made accountable for achieving desired outcomes? How will the collaboration be made accountable for acting prudently, ethically, legally, and with extensive participation from each participating entity? What methods will be used to enforce policy and procedure adherence?

Subsequent to the finalization of the MOUs, formal legal agreements will be drawn among the collaborators that will include program performance metrics (for which see discussion in Form 13) whose accomplishment will be binding on all collaborative members with appropriate fiscal penalties for non-compliance

## New Legal Entity

3. Will a new umbrella legal entity be created as a result of your collaboration?

Yes  
 No

## Payments and Administration of Funds

4. How will you ensure direct payments to providers within your collaboration are utilized for your proposed program's intended purpose? If the plan is to use a fiscal intermediary, please specify.

First Mile Care will be solely responsible for fiscal administration of grant funds and will disperse funds in accord with the State of Illinois' State Directed Payments mechanism. In the legal agreement that will be signed subsequent to the MOU, we will articulate procedures for invoicing and payment based on specific work, activities, and deliverables.

## 4. Racial Equity

### High-Level Narrative

A fundamental focus of healthcare transformation is racial equity. Please provide a high level description of how the design of your proposal incorporates racial equity. (Greater detail will be requested in the questions below.)

The storied history of Chicago's South Side is one of a bustling neighborhood, racially and ethnically diverse, that has faced tremendous economic and race-related hurdles throughout the decades. Originally a home for immigrants working for the meat-packing industry, after the Great Migration, 40,000 Black Americans came to Chicago from the South to seek a better life for themselves, with 78% living in the South Side as of 1910. Chicago was heavily segregated, and a case against housing segregation even went to the Supreme Court in 1940 (*Hansberry v. Lee*), opening up new neighborhoods based on their ruling. After World War II, a great number of upwardly-mobile (and largely white) residents moved to the suburbs, leaving an overwhelming majority Black population. After the Civil Rights movement, many Black people financially capable of doing so moved elsewhere as well, leaving behind one of the most impoverished areas of Chicago. Recently there have been demographic shifts, with large Latinx communities migrating to the South and West Sides, but the population remains majority-non-white.

Income disparity, with fewer jobs available for less pay for minority workers, has had negative effects in all directions of social and economic life. The school system is underfunded, with low graduation rates and even lower rates of admission to college, putting a stumbling block in the path to more profitable careers. Low employment rates can lead to higher crime rates, and during the Black Lives Matter protests in 2020 the South Side was home to many hostile engagements between protesters and the police. A lack of healthy and affordable food options (as well as much of the population reliant on an aging transportation system to travel outside their neighborhood) results in a

Midwestern cuisine that despite many rich culinary traditions remains high in fat, heavy on starch, and reliant on processed foods. The South Side is closer to industrial plants and the air has a higher toxicity than northern neighborhoods. Many lead pipes remain the sole source of drinking water, with state legislation giving the city a full fifty years to replace them. Between toxic air, toxic water, unhealthy food, low employment, tight cash flows, and high crime rates, the South Side can be a stressful place for its residents and the results are negative health outcomes in both the short and long term, all while residents face an expensive and labyrinthian healthcare system.

The goal of this collaborative is to bring localized, laser focus on the particular issue of diabetes prevention. Forty percent of the population is thought to be pre-diabetic in the South Side for all of the reasons listed above. As reported in an article on diabetes in the journal *Medical Care Research and Review*.

“Racial/ethnic minorities continue to suffer a disproportionate burden of disease from diabetes and its comorbid conditions. While the reasons for these disparities are multifactorial, the health care delivery system is most certainly a contributor. As such, health care interventions that target patients, providers, and the health care environment (e.g., payors, health organizations) have the potential to play a significant role in reducing racial disparities in diabetes outcomes.” (Source: Peek, M. E., Cargill, A., & Huang, E. S. (2007). Diabetes health disparities. *Medical Care Research and Review*, 64(5\_suppl), 101S-156S.)

The South Side Diabetes Prevention Collaborative (SSDPC) will bring a community-based care program with a focus on all of the systemic factors that led to the current situation. Employing a local workforce development plan we will hire people within the community to serve as coaches and bring the program to the people, making sure that during their year-long enrollment, clients do not have to travel more than ten minutes to a meeting. Nutrition plans that are developed during the classes will accommodate participants often limited budgets, traditional methods of cooking, and cultural expectations. Local hires will bring cultural competency to the program around matters such as how to modify traditional food choices to keep them as familiar cuisine but more healthy to consume. Exercise plans will be centered on what is feasible for participants in their community for staying active despite a lack of places to exercise, particularly in the winter. We will work with community leaders and other stakeholders to lower stigma around pre-diabetes, educate clients in a manner that is dignified and respectful, and do whatever we can to address the needs in this underserved community. Racial equity means meeting people where they are and giving them the tools to lift themselves up and stay healthy and prosperous.

### Racial Equity Impact Assessment Questions

1. Which racial/ethnic groups may be most affected by and concerned with the issues related to this proposal?

The South Side of Chicago is a majority Black/Latinx population. The 25 zip codes served by the 5 FQHC's in our collaboration have a total population of just over one million people in the 2010 census. The population was reported as 62% Black or African American and 24% Latino. The average income for our target area is \$42,174 versus Cook County's average of \$69,429 (2019 ACS Estimates), i.e., 39% lower.

2. Have stakeholders from different racial/ethnic groups — especially those most adversely affected or from vulnerable communities — been informed, meaningfully involved and authentically represented in the development of this proposal? Who's missing and how can they be engaged?

The collaborative is well established in the communities through the work of the 5 FQHCs. The need for preventative care and specifically DPP was established in their masterplans. This proposal works to provide the DPP care at the local community level for their entire population. We will continue to engage stakeholders in the South Side community, primarily through pre-existing social networks such as community organizations, faith-based institutions, and schools.

3. Which racial/ethnic groups are currently most advantaged and most disadvantaged by the issues this proposal seeks to address? How are they affected differently? What quantitative and qualitative evidence of inequality exists? What evidence is missing or needed?

South Side Chicago contains a small middle-upper class community centered around and often employed by the University of Chicago campus. These fortunate members of the community are atypical in having excellent employer paid health insurance and can be expected to be among the most advantaged populations in the service area. Our program design does not force serving population. The disadvantaged populations are primarily Black/Latinx. These populations are adversely affected by many factors that can be broadly encompassed by the designation social determinants of health. See our extensive discussion of these below in Form 9. One shortcoming of which we are aware of going into the project is that the FQHCs do not currently have adequate Spanish speaking staff which limits their ability to deliver services to monolingual Latinx, we have taken cognizance of this by planning to hire Spanish speaking bi-lingual staff as need for our services.

4. What factors may be producing and perpetuating racial inequities associated with this issue? How did the inequities arise? Are they expanding or narrowing? Does the proposal address root causes? If not, how could it?

A large percentage of the population in all targeted zip codes are either Black or Latinx. These traditionally-underserved populations, packed in high-density areas with poor schools, transportation, and other services because of real estate redlining, suffer from a variety of medical conditions at higher proportion to the general population of Chicago. Because of the prohibitive cost of healthier food choices and lack of affordable places to exercise (particularly in the winter), the population is particularly vulnerable to diabetes and other health problems due to poor nutrition and lack of exercise. These problems can only be partially addressed by education; clients have to be empowered and given reasonable goals to improving their health situations while taking into account income-related barriers to good health.

The DPP curriculum engages with each participant to create an individual plan for exercise and eating. Because the programs take place in the neighborhoods where they live, the plans deal with the constraints they face. Reversing prediabetes takes finding a way to stay active, building up to 150 minutes/week of activities like walking and 5% weight loss. Much of the need during the year-long program is providing the information that removes the stigmas or myths. We believe becoming a healthier person is possible while not giving up the traditional foods you love, without performing extreme amounts of exercise, and without unrealistic and unnecessary standards for body image and weight. By having participants meet in a safe environment with a coach and people who are like themselves, the program reinforces powerful new visions of a healthy self.

5. What does the proposal seek to accomplish? Will it reduce disparities or discrimination?

Due to factors discussed above, this population has a high rate of pre-diabetes and inadequate education on the condition and how to live with it, eliminate it, or at least prevent the advancement to full diabetes. This proposal will directly address the needs of that population by educating participants on prediabetes and working with them to develop health plans that fit their personal schedules and responsibilities. It will reduce disparities in the South Side service area population as compared to the general population of Chicago, which has a lower instance of pre-diabetes diagnosis.

6. What are negative or unforeseen consequences and positive impacts/opportunities for equity as a result of this proposal? Which racial/ethnic groups could be harmed or could benefit? How could adverse impacts be prevented/minimized and equitable opportunities be maximized?

We do not foresee any negative consequences to creating a pre-diabetes prevention program with considerable community outreach. It will serve any at-risk members of the population who are not adequately served or reached by previous providers. Attendance is voluntary and the program is custom-tailored to the needs of the client in their home location. Working within the community – within the first few miles of the client's home address – will minimize the inconvenience that often prevents clients from seeking preventative care or sticking with a year-long program.

7. Are there better ways to reduce racial disparities and advance racial equity? What provisions could be changed or added to ensure positive impacts on racial equity and inclusion?

Any elements of the proposal which may be lacking in the planning stage but become evident in implementation as we develop deeper ties with the community and our clients will be humbly and appropriately addressed as part of our commitment to continuous quality improvement (CQI). The DPP program will be delivered over 5 years in a form that ramps up from 560 in year one to 1792 in Year 5. This is purposefully done to ensure we can learn what works in recruiting people for the program, delivering the program, and retaining people throughout their year-long commitments to the program. We will be working together as a collaborative to make any necessary changes and incorporate any learning (a core governance function: see discussion in Form 3 above).

We will be tracking health results such as Hemoglobin A1c for participants and compare those results versus the people who qualify but do not choose to participate. Additionally we will work to capture any other participant health improvements relative to the non-participants. This analysis will show us other benefits or highlight areas for improvement areas which will allow us to improve the efficacy of the program throughout the 5 year period.

8. Is the proposal realistic, adequately funded, with mechanisms to ensure successful implementation and enforcement? Are there provisions to ensure ongoing data collection, public reporting, stakeholder participation and public accountability?

The proposal is modeled on programs run in similar communities in other regions of the United States, and enhances the currently funded South Side Healthcare Collaborative (SSHCC) so First Mile Care and its collaborators are accustomed to and have a process for data collection, reporting, and stakeholder participation, and public accountability. These metrics will be outlined in other sections in the proposal.

9. What are the success indicators and progress benchmarks? How will impacts be documented and evaluated? How will the level, diversity and quality of ongoing stakeholder engagement be assessed? The goals of the program are to achieve the CDC's targets for activity, weight loss, and retention for our participants. Additionally we plan to measure Hemoglobin A1c prior to participation, after 8 weeks, and after a year. This serum sampling shows lowering the risk of diabetes. Additionally we will track other health outcomes with the FQHC's analysis of the health care medical records. We expect to see reduced health issues during the period following participation in the program. We will work to quantify this as both improvements in general health as well as calculate savings to the health system due to participation in the program.

## 5. Community Input

### Service Area of the Proposed Intervention

1. Identify your service area in general terms (e.g., "West Chicago", "East St. Louis Metro Area", "Southeastern Illinois").

South Side Chicago

2. Please select all Illinois counties that are in your service area.

Cook

3. Please list all zip codes in your service area, separated by commas.

60406, 60409, 60411, 60419, 60426, 60428, 60438, 60455, 60469, 60472, 60473, 60617, 60619, 60620, 60621, 60628, 60629, 60632, 60633, 60636, 60637, 60643, 60649, 60803, 60827

## Community Input

1. Describe the process you have followed to seek input from your community and what community needs it highlighted.

The South Side Diabetes Prevention Collaborative (SSDPC) is building and expanding on the accomplishments of the South Side Healthcare Collaborative model previously funded by Illinois Department of Healthcare and Family Services (DHFS) in the HTC competition's First Round. In order to address long-term health disparities that have plagued the South Side community, the applicant entities, including our FQHCs, cooperated to consult with more than 800 South Side healthcare providers, faith leaders, community organizations, elected leaders, patients and residents in a thorough health care needs analysis. The FQHCs affirm that they realize that adult-onset type-2 diabetes is a serious health issue for many of the thousands of patients they are currently serving. It is a costly medical condition which too often leads to many additional, very serious medical problems that compromise quality of life and even foreshorten it. They understand that it is preceded by clinically determined pre-diabetes that left untreated is likely to lead to full-blown diabetes. They currently lack adequate resources to identify individuals as pre-diabetic and to offer them effective evidence-based prevention and early intervention services (PE&I). The FQHCs therefore are excited to be joining First Mile Care in our HTC application to DHFS as First Mile can offer an evidence-based program that has been shown to reduce participants' risks of developing type 2 diabetes by 58% (71% for participants over 60) by helping them take the small steps needed to make healthy choices that can keep a diabetes diagnosis at bay for a lifetime.

The Illinois Department of Public Health further affirms the seriousness of diabetes as a public health problem (see <https://dph.illinois.gov/topics-services/diseases-and-conditions/diabetes.html>). In Illinois, approximately 1.3 million adults (12.5% of the population) have diabetes, but roughly 341,000 of those (26.2% of the diabetic population) don't know they have diabetes. Diabetes is the seventh leading cause of death nationally as well as in Illinois. Individuals with diabetes are at an increased risk for heart disease, stroke, blindness, kidney failure, dental disease, and lower extremity amputations (not related to injuries). Diabetes and its complications occur among all age, racial, and ethnic groups, but African Americans, Hispanic/Latino Americans, and Native Americans are most at risk. The predecessor condition is pre-diabetes. It is estimated that 84 million Americans have pre-diabetes, of which 3.6 million live in Illinois.

The 5 FQHC's in our collaborative have already come together to address the unmet needs of the South Side communities they serve. They conducted extensive community outreach to create their master plan for supporting the community. Reaching beyond the primary and specialty health care services, these organizations have formed this collaborative to address diabetes in the community by adding Diabetes Prevention for the full community they serve. The following is a summary of the process that was used in defining the community needs by engaging with the community.

*Direct Community Input.* The South Side Healthy Community Model was built on community input. From its inception and over the past eight months, more than 900 South Side healthcare providers, faith leaders, community organizations, elected leaders, patients, and residents have been actively engaged in an effort to gather thoughts and ideas on what makes a healthy community. This input formed the foundation of the Healthy Community Model, designed to address long-time health disparities that have plagued the South Side community.

In September 2020, the first South Side Health Transformation community meeting was held. Nearly 150 South Side community stakeholders gathered virtually in a townhall format and in ten smaller break-out rooms to offer their perspectives on healthcare needs in South Side neighborhoods. Community leaders then hosted 12 smaller community listening sessions over the next several weeks where residents could share their personal stories and the need for better access to quality care in their neighborhoods.

- A website was created where visitors can learn about the needs on the South Side, explore summary reports from the listening sessions, find answers to their questions, watch videos featuring community testimonials, review aspects of the transformation model, and share their feedback through an open Google Form.
- A broad-based community survey was conducted to better understand the gaps residents experience when receiving care on the South Side. The survey was available both digitally and in hard copy at 12 convenient locations, like South Side churches and community hubs, and 240 community members shared their feedback.

- On October 8th, 2020, a large group community update was held and attended by more than 100 community stakeholders to introduce an early concept for a transformation model and allow more community input, feedback and suggestions.
- In addition, a community stakeholder email listserv of more than 900 people was amassed through which communications were deployed through a regular cadence of emails and Zoom reconvening sessions to share project updates.

Throughout this process, many community leaders, such as pastors of significant South Side congregations and directors of community organizations, have been integral partners in engaging the community, often championing the South Side Health Transformation Project to contemporaries, colleagues, community members, personal and professional networks, and the media. Nearly 40 community partners wrote their elected representatives, urging them to vote to approve the allocation of \$150 million in state and federal funding earmarked for health transformation. Additionally, there have been 11 news stories illustrating the goals and grassroots nature of the project—several include quotes from community leaders, and one op-ed was authored by four particularly involved community advocates.

As we implement the DPP program to meet the community needs we will continue to build on this initial outreach working to ensure the needs are being met in a way that builds the local community. Our hiring and training of coaches will be people from the community and the classes that are held in person will invest in the community, paying for the spaces where we meet. Throughout the 5-year period we will seek out further input from the community on the success and needs for improvement in the program offerings.

Affirming their commitment to participate in the project and their keen appreciation for the need for it, are formal Letters of Intent from each of the FQHCs and other minority led community partners which are uploaded below.

2. Please upload any documentation of your community input process or findings here. (Note: if you wish to include multiple files, you must combine them into a single document.)

Form 5 Partner Intent Population Health Collaborative-SSDPC\_FINAL  
(Redacted versions without signatures as an Exhibit 1)

### Input from Elected Officials

1. Did your collaborative consult elected officials as you developed your proposal?  
 Yes

- 1A. If you consulted Illinois federal or state legislators, please select all legislators whom you consulted.

If you consulted local officials, please list their names and titles here.

Slaughter, J. - Ill. Representative - 27th State Representative District 1B.

Please upload any documentation of support from or consultation with elected officials.  
(Support letter attached as an Exhibit 2.)

Slaughter, J. - Ill. Representative - 27th State Representative District 1B.

## 6. Data Support

### 1. Describe the data used to design your proposal and the methodology of collection.

In 2002, the New England Journal of Medicine (Vol. 346.6) published an article entitled, “Reduction in the Incidence of Type 2 Diabetes with Lifestyle Intervention or Metformin.” In it, the study patients were assigned a lifestyle-modification program using individualized lifestyle counseling with a goal of at least 150 minutes of activity per week and a weight loss of at least 7 percent. Forty-five percent were members of minority groups. After almost three years, the follow-up results showed a reduction of incidence by 55 percent compared to the placebo population. This program of diet and exercise was recommended over the use of diabetes medications such as metformin when possible: “Since current methods of treating diabetes remain inadequate, prevention is preferable.”

This article was massively influential and remains highly cited today. In 2010, The CDC used the study results to create the National Diabetes Prevention Program (National DPP) (<https://www.cdc.gov/diabetes/prevention/index.html>). The qualifications for CDC recognition as a DPP provider are posted on the agency’s website and are as follows:

- Use of a CDC-approved curriculum. You can use a curriculum developed by CDC, or you can develop your own or use that of another organization (with permission), as long as CDC approves it. View the list of topics covered in the CDC-approved PreventT2 curriculum pdf icon[PDF – 179 KB].
- Ability to begin offering the lifestyle program within 6 months of receiving approval from CDC.
- Capacity and commitment to deliver the program over at least 1 year, including at least 16 sessions during the first 6 months and at least 6 sessions during the last 6 months.
- Ability to submit data on participants’ progress—including weight and physical activity minutes collected at each session—every 6 months.
- Trained lifestyle coaches who can help build participants’ skills and confidence to make lasting lifestyle changes.
- Designated individual(s) to serve as the diabetes prevention program coordination.” (<https://www.cdc.gov/diabetes/prevention/requirements-recognition.htm>).

First Mile Care’s DPP meets all of these requirements for full recognition status by the CDC and intends to bring this extensively evidence-based method to Chicago. In its prior implementations it has consistently met the CDC performance criteria for participant weight loss, activity and retention.

Since CDC standardization in 2010, many DPPs have been established across the country, including some in Chicago. But over a decade of operations, these programs rely on physicians or other care providers referring patients to them and have yielded very mediocre service outcomes. First Mile Care’s new interventions and delivery redesigns in several comparable implementation sites around the country have achieved dramatically better service outcomes, using a concentrated approach that generates demand and supply for DPP simultaneously as well as integration with the overall health plans of the participants (see detailed discussion in Form Two above).

With our collaboration in Chicago, we will be able to go beyond the CDC’s requirements in assessing health by also estimating short-term improvements in health and reduction in cost due to healthier lifestyles. This collaboration will allow us capture those improvements in a quantitative way to show that the program investment pays out in the near term as well as through the longer term reduction in the prevalence of Type 2 Diabetes, a disease that has serious health effects and costs \$16,000 a year to manage.

### 2. Attach the results of the data analyses used to design the project and any other relevant documentation. (Form 6 NEJM DPP article (NIH)\_6 attached as an Exhibit 3)

## 7. Health Equity and Outcomes

1. Name the specific healthcare disparities you are targeting in your service area, including by race and ethnicity. Describe the causes of these disparities that your project specifically seeks to address and explain why you have chosen to address these causes.

The specific healthcare disparity targeted in the broadest sense is chronic disease morbidity/mortality. The South Side's African American and Latinx communities are disproportionately affected by very poor outcomes in conditions that fall under this category. One contributor to these outcomes is diabetes. Our target population has not had access to diabetes prevention support in any substantial way. Change across the healthcare and social service delivery ecosystem is necessary to change this as a contribution to addressing chronic disease morbidity/mortality.

2. What activities will your collaborative undertake to address the disparities mentioned above? What immediate, measurable, impacts will follow from these activities that will show progress against the obstacles or barriers you are targeting?

Activities to address the disparity mentioned above will take several forms:

(1) Recruiting and training neighbors in the Southside Community to act as coaches/trainers and recruiters/enrollers in the conduct of an evidence-based program. Coaches will have formal education and/or experience in community healthcare. They will have experience and additional training in group facilitation. They will be trained in evidence based or best practices such as Motivational Interviewing and Stages of Change (identifying an individual's readiness for change). As a local citizen the coaches will be familiar with environmental challenges facing participant, including seasonal constraints, COVID impacts, and the availability of locally accessible food and recreational resources.

(2) Provision of a 22 session per year group class/coaching activity for each qualifying participant to impart critical information and facilitate group support for accomplishment of individual objectives (including weight loss, activity and new nutritional decision making) leading to prevention of diabetes.

(3) Creating and increasing access to coaching/classes for adults and older adults by (a) development of coaching/class locations for group sessions that are accessible to participants within 10 minutes and in time-slots sufficient in time of day and day of week to accommodate participants' attendees' availability and (b) scaling this development throughout the course of the project to address the need throughout all 15 zip codes of the Chicago Southside health service area.

Content of the coaching/class sessions and will include: Exercise: strategies for accomplishing physical exercise realistic in response to the external conditions of the community and consistent with the social norms of the attendees, trained coaches and neighborhood support staff, including exercise as stress management. Eating habits: Raising awareness about attendees current eating habits, promoting the examination of underlying assumptions in those habits and facilitating new choices and tradeoffs. Information will be conveyed via coaching, small groups of fellow participants (neighbors who are "people like me) in person or via live video. Webinars, blogs, etc. will also be used as teaching aides. Keys to participant success include accountability to the peer group. This accountability is motivated by the "cheer leading," non-judgmental nature of the group, its motto of "forgive yourself" and objectives pursued with "baby steps" that are realistic for each participant. E.g. one minute of exercise may be the equivalent of 10 minutes for another. Each participant develops his own eating/exercise plan. As he/she checks in weekly about progress learning is achieved as a balance between group interaction and the coach's inputs

Outcome measures will be discussed in detail in below in Form 13. Metrics will include sustained class attendance, weight loss, increase in health physical exercise habits, and blood testing to confirm resolution of pre-diabetes. Equity and community-based support growth metrics will include expansion of conveniently available classes, increases in local employment and increased service coverage and culturally competent community-based healthcare service for the South Side population.

### 3. Why will the activities you propose lead to the impact you intend to have?

The organized learning process in communities adversely impacted by health disparities cannot even begin unless a sustainable system is put in place to identify participants, engage with them, and provide them with convenient enrollment and sessions. First Mile Care's system has been tested in several prior implementation sites in the U.S. comparable in demographics to Chicago's South Side. Populations similar in demographic (gender, race, age range, social economic determinants, and geography) have achieved successful outcomes along all measures that will be used in this project. The same can be said for the strategy to hire, train and implement coaches (delivering information relevant to the local conditions and needs of the participants) and recruiter/enrollers.

## 8. Access to Care

1. Name the specific obstacles or barriers to healthcare access you are targeting in your service area. Describe the causes of these obstacles that your project specifically seeks to address and explain why you have chosen to address these causes.

Barriers to healthcare access for our service population are massive, persistent and have proven difficult heretofore to address. Our project cannot address all of them but it does offer responses to some of them: lack of knowledge about being prediabetic as well as of the risks of being prediabetic for future health, scarcity of healthy food options in the neighborhood, lack of community/neighborly support for healthy eating and living, and transience of the service population. We have chosen these issues to address because they are eminently addressable in a program of modest per-person cost yielding substantial potentially life-term benefits with a reasonably short-term time commitment from participants.

2. What activities will your collaborative undertake to address the disparities mentioned above? What immediate, measurable, impacts will follow from these activities that will show progress against the obstacles or barriers you are targeting?

The strategically located FQHCs in the South Side Healthcare Collaborative (SSHC) are already offering convenient access to primary and specialty care for our target population, including diabetes treatment. Our lacking is a strong preventive focus for this debilitating and expensive disease. The South Side Diabetes Prevention Collaborative (SSDPC) will build upon the success of the 5 FQHCs with their current client base to provide an evidence-based DPP that will increase participant knowledge of the dangers of diabetes and the benefits of prevention, make them aware of healthy food options they may have been unaware of, build strong community and neighborhood support for healthy living, and provide program flexibility to serve even highly transient members of the service population. Metrics for these activities are discussed below in Form 13.

3. Why will the activities you propose lead to the impact you intend to have?

As a CDC evidence-based model, DPP is already well-proven to help program participants to address the obstacles and barriers to health care identified above. First Mile Care's experience-based delivery redesigns (discussed in detail above in Form 2) very much increase the likelihood of successful participant outcomes. Targeted recruitment will help assure that the most motivated individuals who are most likely to persist over the 22 week course of the program (e.g., those over 45) and therefore maximally benefit from it are chosen first and then reaching out to others in the registry in the later years of the project. Convenience to the consumer in service locations and times will also promote program completion and acquisition of intended benefits. We expect to have from three to five times as many program delivery sites as are now available from the five FQHCs (we aren't counting on using FQHC locations because of availability constraints or appropriate sizing for sessions). We anticipate needing to offer about five different meeting times per site to meet people's schedules for each zip code. Finally, neighbors helping neighbors at the zip code level will build participant solidarity and pride in accomplishments.

## 9. Social Determinants of Health

1. Name the specific social determinants of health you are targeting in your service area. Describe the causes of these social determinants that your project specifically seeks to address and explain why you have chosen to address these causes.

The South Side Healthcare Collaborative (SSHC) has decided to focus on three social determinants of health: food insecurity and inaccessibility of nutritious food choices, transportation, and employment. The roots of all these adverse determinants can be found in the history of intense racial discrimination and economic adversity that characterize the South Side (see discussion in Form 4 above). Weak consumer purchasing power has long been a disincentive for mainline, for-profit grocery stores to locate in the South Side. Automobile ownership is low, owned vehicles older and more problem-prone, many residents do not drive and public transit is inadequate or very inefficient for making trips far from home, and very many people do not have jobs that offer employer paid or subsidized health care. Overall, a long history of inequity and disinvestment in the neighborhood has yielded poverty rates of over 60% in some parts of the South Side.

*Rationale for Selection.* The South Side Healthy Community Model Collaborative, of which the 5 FQHCs in our collaborative are members, has already determined that these social determinants of health have had a high, negative impact upon individual residents' access to health services and the overall health of the South Side community as well. Our DPP will function as a very useful and needed prevention-oriented "plug in" extension to the larger collaborative's concurrent efforts in the community that have a decidedly treatment-focused approach generally speaking.

2. What activities will your collaborative undertake to address the disparities mentioned above? What immediate, measurable, impacts will follow from these activities that will show progress against the obstacles or barriers you are targeting?

### Activities to Address Disparities

*Food Insecurity:* Coaches in neighborhood classes helping participants to optimize selections from available food sources that are known to lead to improved health and promote diabetes prevention.

*Transportation:* Minimizing participants' burden to access public or private transportation by locating classes with 10 minutes of their homes. In addition we have budgeted for transportation needs to support participant program retention. We are planning to use a local BEP transportation provider Around the Clock Transportation.

*Employment:* Most directly, program staffing, nearly all of it local, will provide new employment opportunities for adults in the service area community. Indirectly and over time enhancing residents' ability to seek work and maintain work as health conditions constraining ability are reduced or prevented from emerging. and for those employed, attendance and alertness of safety risks. That program services will be offered within 10 minutes of home and at times and days convenient to their employment and domestic needs will assure program participation will not adversely affect participants' ability to maintain current employment positions.

### Measurable Impacts

We will track and measure the model's success using four metrics:

1. Number of patients assisted in overcoming one or more adverse social determinants of health.
2. Percentage of participants who can access program services within 10 minutes of their home.
3. Number of participants engaged in and completing DPP.
4. Number of new jobs created by our collaborative over the five program years.

### 3. Why will the activities you propose lead to the impact you intend to have?

Prior DPP implementations in locations socio-economically comparable and as racially diverse as South Side Chicago, such as the disadvantaged neighborhood served by Hope Clinic in Houston, Texas, are yielding success in achieving the measurable impacts listed above.

## 10. Care Integration and Coordination

### 1. Describe how your proposal improves the integration, efficiency, and coordination of care across provider types and levels of care.

A key objective of the South Side Healthcare Collaborative (SSHC) program that our collaboration is designed to supplement as a “plug in” supplementary but essential component, is to reduce fragmentation and improve coordination of care and services across community sites, primary care, specialty care, acute care and post acute or non-acute care. This proposal integrates with and strengthens the South Side care community’s capacities by bringing prevention and early intervention (P&EI) services focused on diabetes to the area for the first time. First Mile’s DPP always leverages the existing healthcare system in implementation sites. The program starts with the trusted relationships patients already have with their primary care providers and extends those relationships deeper into the community to assure, over the course of a year of program participation, those patients have long term care that will prevent progression into diabetes.

First Mile Care’s recent implementation in the Detroit, Michigan area is illustrative of impact. First Mile’s local DPP received referrals from 750 people over 6 weeks in a single zip code that were all known to have pre-diabetes based on their medical records. They all received a letter by mail from their primary care physicians explaining how they could benefit from the DPP at no cost. Nearly three-quarters of them (550 patients) responded during the 4-week outreach, and 88 of them subsequently enrolled in DPP classes. The program hired 5 coaches to run the classes and 2 people to manage the outreach and enrollment, all locals. Care was taken that classes were scheduled at locations no more than 10 minutes distance from where participants lived and at times convenient for them, with times and dates changed to meet the needs of the enrollees.

For the Chicago Southside implementation, three patient populations will serve as target audiences for recruitment into First Mile’s program: 1) patients currently in our system who are known to us as at risk of diabetes; 2) patients previously identified as at risk with whom we have lost contact; and 3) current patients who have not yet been screened clinically with glucose and/or A1c testing for pre-diabetes. First Mile Care will be responsible for recruitment and engagement of candidates so referred to DPP. First Mile Care will pay for A1c testing, the “gold standard” for accurate identification of pre-diabetic individuals, for those referral candidates who have not previously been so tested. First Mile Care will utilize HTC grant funds to pay for all costs of DPP for referred participants and—whenever possible—insurance providers including Medicaid. The undersigned FQHCs will not be obligated for any of these costs. First Mile Care will share HIPPA-compliant testing results and program outcomes with the referring FQHCs at no cost to them.

### 2. Do you plan to hire community health workers or care coordinators as part of your intervention?

Yes

#### 2A. Please submit care coordination caseload numbers and cost per caseload (stratified by risk, if applicable).

The average amount of people that a coach will manage is around 5-8 classes of 10 person classes on a rolling basis during a program year. Each coach will run an estimated four classes a week (since coaches will be working part time, their actual work loads will be self-chosen). Additional patients will be accommodated in new groups, so a coach’s care load will eventually be a mix of new and previously established groups. Each participant will be seen 22 days per year in group. Medicare recognizes the value of DPP but pays \$660 per person only for each participant who completes the cycle of 22 meetings in a year. That’s because DPP is delivered not on a traditional “fee for service” but a “pay-per- performance” payment model. The collaboration will work with Medicaid and other, private

insurers to maximize cost reimbursement opportunities in order to conserve project funds and extend their reach to participants who are uninsured.

3. Are there any managed care organizations in your collaborative?

No

3A. If no, do you plan to integrate and work with managed care organizations?

- Yes

3B. Please describe your collaborative's plans to work with managed care organizations.

Based on the success of this collaboration we will reach out to managed care organizations serving the South Side communities who are interested in diabetes prevention. This is in fact an important part of our sustainability plan. The current collaborators represent 100,000 of the 1 million people in the South Side service area so our success could rapidly scale to 10x the initial target population. See discussion in Form 16 below.

## 11. Minority Participation

**1. Please provide a list of entities that will be a part of your collaboration/partnership that are certified by the Illinois Business Enterprise Program (BEP) and/or not-for-profit entities majorly controlled and managed by minorities that will be used on the project as subcontractors or equity partners.**

List entities here:

The South Side Diabetes Prevention Collaborative (SSDPC) includes the following not-for-profit entities, all of them FQHCs, that are majorly controlled and managed by minorities:

Christian Community Health Center  
Beloved Community Health Center  
Chicago Family Health Center  
Family Christian Health Center  
TCA Health Inc.

In addition to the collaboration partners above we will be working with BEP-certified entities as vendors to support the program execution. This includes:

Capgenus  
Around the Clock Transportation  
RLM Media  
PCG Consulting Group

2. Please describe the respective role of each of the entities listed above, and specify whether they will have a role only during the implementation of your proposal or if they will have a role in the ongoing operation of your transformed delivery system.

As described above in Form 3: Governance Structure, these entities, as members of our collaborative will be responsible for:

- Working with First Mile Care to identify patients in three patient populations as target audiences for recruitment into First Mile's program: 1) patients currently in our system who are known to us as at risk of diabetes; 2) patients previously identified as at risk with whom we have lost contact; and 3) current patients who have not yet been screened clinically with glucose and/or A1c testing for pre-diabetes.
- Maintaining patient referral streams to First Mile Care's DPP during the five year life of the grant and share relevant HIPPA compliant patient data important for the program's success and evaluation.

- Build out the infrastructure to support the project's administration, operations, report running, testing, data analysis, clinical support and other administrative needs to support the administration for the DPP program.
- Invest in programmatic innovations that will support the sustainable delivery of preventative care to the collaborative's patients past the grant timeline.
- Participating in a coalition governance structure—to be finalized post-award—for the purposes of continuous quality improvement, responsiveness to patient feedback, and exploration of sustainability options for DPP in the post-grant period.

As can readily be seen, these non-profit minority entities will have important roles not only during the implementation of our program but also in the ongoing operation of a transformed delivery system in South Side Chicago.

Throughout the execution of the program the SSDPC will seek to find and use BEP entities and vendors to fulfill our needs. We have identified 3 key vendors that we are already planning to use. In addition to the collaboration partners above we will be working with BEP-certified entities as vendors to support the program execution. This includes Capgenus, Around the Clock Transportation, and RLM Media.

Capgenus will aid the FQHCs in meeting administrative and analytical program functions.

Around the Clock Transportation will provide assistance for participant retention by offering transportation to program service sites where needed. RLM Media will aid participant recruitment through targeted media outreach.

## 12. Jobs

### Existing Employees

1. For collaborating providers, please provide data on the number of existing employees delineated by job category, including the zip codes of the employees' residence and benchmarks for the continued maintenance and improvement of these job levels.

The five FQHC members of our proposed SCDPC make up a major portion of the current employee base of the larger South Side Healthcare Collaborative. The recently funded HTC round 1 proposal includes a detailed accounting of these employees delineated by job category including the zip codes of employees residents. These tables are represented again below in our proposal. These tables show 12,530 clinical employees, 2,699 non-clinical employees, and 15,229 employees total. While this is a larger base of employees that are currently working for the FQHCs in our collaboration, it is anticipated that eventually the other members of the SSHC will be interested in offering DPP services based on our success.

Attached is the comprehensive list of SSHCO employees submitted in conjunction with the HTC 2021 First Round Competition. (Original submission included an attachment that is redacted from this document).

### New Employment Opportunities

2. Please estimate the number of new employees that will be hired over the duration of your proposal.

3. Describe any new employment opportunities in the future alignment of your proposal and how those opportunities reflect the community you serve.

In order to deliver the DPP, First Mile Care is proposing a program design that will create 35 Coaches over the 5 years to support the 5,000 participants and we will engage a local South Side Call Center Operation and hire 4 full-time equivalent Participant Engagement Assistants (PEA) to conduct outreach and enrollment. Additionally, we will be hiring 5 management positions including: 1 Regional Coordinator, 1 Program Manager, 1 Master Coach, 2 Engagement Managers.

The FQHCs will be building the infrastructure to support their program related responsibilities. We expect they will add a total of 3 managers to their combined organizations to do this.

In total this will be 47 new positions created in the South Side Chicago community to ensure delivery of this program. The overwhelming majority of these jobs—if not all—will be local hires, consonant with the community-based First Mile Care DPP model.

4. Please describe any planned activities for workforce development in the project.

First Mile Care will devote substantial amounts of grant funds to train local individuals to be qualified coaches for delivering DPP. As the program rolls out and expands, these coaches will qualify for management personnel positions, both during and post-project.

### 13. Quality Metrics

#### Alignment with HFS Quality Pillars

1. Tell us how your proposal aligns with the pillars and the overall vision for improvement in the Department's Quality Strategy.

Our SSDPC is structured as a "plug in" supplementary but essential component of diabetes prevention to support the achievement of the goals and objectives of the South Side Healthy Community Model (SSHCO), a first round HTC awardee of the Illinois Department of Healthcare and Family Services. The SSHCO is itself aligned with the goals of the Department's Quality Strategy as enumerated in items 1-12 of the Health and Family Services Quality Strategy document under the categories of better care, healthy people/healthy communities and affordable care. Of the 12 items, our SSDPC is directly in support of nine: 1) improve population health, 2) improve access to care, increase effective coordination of care, 3) improve participation in preventive care and screenings, 4) create a consumer-centric healthcare delivery system, 5) identify and prioritize reducing health disparities, 6) implement evidence-based interventions to reduce disparities, 7) invest in the development and use of health equity performance measures, 8) incentivize the re-education of health disparities and achievement of health equity, and lastly 9) transition to value-and outcome-based payment.

**Does your proposal align with any of the following Pillars of Improvement?**

2A. Maternal and Child Health?

No

2B. Adult Behavioral Health?

No

2C. Child Behavioral Health?

No

2D. Equity

Yes

Equity: Propose measurable quality metrics you propose to be accountable for improving. You should choose at least one metric from the quality strategy.

As the HFS Quality Strategy framework prioritizes by analyzing data relating to program equity to strategically pinpoint improvement needs, our program will collect data to identify all persons within the scope of the SSHCO service area who are in need of pre-diabetes intervention. Implementation will be based on the employment of lay members of the community to act as coaches and instructors and a model for education and retention of these members of the program staff in the pursuit of equity. Our program will take steps to identify appropriate candidates for service who already exist in the specific neighborhoods where health inequities are highest. See Form Two above for how program participants will be recruited and engaged by a support system comprised primarily of members of their own community to sustain attendance and completion of prevention coaching/classes and to attain personal objectives, relevant to diabetes prevention, including weight loss, improvement of nutrition and increase in healthy physical activity. The proposed metric is as follows:

Metric	Improvement Objective	Time Interval
Expansion of Local Hires	21 New Hires	Year 1
	New Hires Maintained	Year 2
	7 New Hires	Year 3
	7 New Hires	Year 4
	12 New Hires	Year 5

2E. Community-Based Services and Supports?

- Yes
- 

Community-Based Services and Supports: Propose measurable quality metrics you propose to be accountable for improving. You should choose at least one metric from the quality strategy.

Measures for this pillar are included as reporting measure until baseline rates and health plan performance on the measures are established.

Page 30 of 51 Our program design is strongly supportive of the Overall Vision for Improvement of this pillar, namely, Serve More People in the Settings of Their Choice, documented by increasing the percentage of adults receiving care in home-or community-based programs to maximize the health and independence of the individual. An unvarying performance standard will be making prevention coaching/classes available within 10 minutes travel time and providing time slots available to them throughout the day and week to accommodate their schedules. Proposed equity metrics will be as follows:

Metric	Improvement Objective	Time Interval
1. Growth in Participant Enrollment	+ 560	Year 1
	+ 672	Year 2
	+ 896	Year 3
	+ 1232	Year 4
	+ 1792	Year 5
2. Expansion in Zip Codes Served	5 served	Year 1
	10 served	Year 2
	15 served	Year 3
	20 served	Year 4
	25 served	Year 5

- 2. Will you be using any metrics not found in the quality strategy? Yes
-

**South Side Diabetes Prevention Collaborative**  
First Mile Care, Inc.

3A. Please propose metrics you'll be accountable for improving and a method for tracking these milestones.

The program will be collecting key patient information regarding propensity to develop diabetes as participants enroll if they don't already have it from previous tests ordered by their referring FQHC. or get it going in from their PHI. The FQHC will have other relevant information if they have additional problems during their period of participation. For its part, DPP will collect information on patient weight, activity, and attendance as per CDC protocol. These are also the measures recommended for good diabetes prevention in the *New England Journal of Medicine* article that effectively established DPP as a Best Practice (see discussion in Form Six above). Participants who commence overweight will be expected to lose 5% of their body weight and maintain 150 minutes of activity per week. They will create weekly action plans and discuss them with other participants and their coach at the meetings. First Mile will not offer blood tests but will work with the FQHCs to obtain baseline information and to assess participant compliance and overall program success. Use of DPP as a Best Practice model can be expected to yield other positive participant health changes, like declines in baseline hypertension. Though these are not part of the CDC protocol, First Mile will work with the collaborating FQHCs to assess the impact these may have on the total overall health of program participants. Accordingly, DPP is proposing the following as Additional Metrics:

<b>Metric</b>	<b>Improvement Objective</b>	<b>Time Interval</b>
Weight Loss	At least 5%	After 12 months participation in the program
Weight Loss when combined with Physical Activity	At least 4% and at least 150 minutes / week on average of PA minutes	12 months after each group of participants commences services
Reduction in HbA1C	At least 0.2 % reduction	Values collected from participants in months 9-12
Attendance Retention	Minimum 50%	At the beginning of the 4th month since first session
Attendance Retention	Minimum 40%	At the beginning of the 7th month since first session
Attendance Retention	Minimum 30%	At 10th month since first session

**14. Milestones**

For all activities described in your proposal, please provide a calendar of milestones to show progress (e.g., when IT will be purchased, when IT will be operative, when construction projects will begin and end, when people will be hired, etc.) The timeline should be in months from award.

<b>DPP Milestones</b>		
<b>Activity</b>	<b>Begin</b>	<b>Complete</b>
MOU's with Collaborators for Program Implementation	Year 1, Month 1	Year 1, Month 1
Business Associates Agreement	Year 1, Month 1	Year 1, Month 1
Recruitment and Hiring of Regional Coordinator, Master Coach and Engagement Manager	Year 1, Month 1	Year 1, Month 3
Engagement with doctors/ health care providers and orientation to DPP	Year 1, Month 1	Year 1, Month 3
Service Population Identification StageOne Registry Created	Year 1, Month 1	Year 1, Month 3
Recruitment and Hiring Recruiting and Enrollment staffs (PEAs)	Year 1, Month 1	Year 1, Month 4
Recruitment and Hiring of Coaches	Year 1, Month 1	Year 1, Month 6
Regulatory Compliance Training	Year 1, Month 1	Ongoing
DPP Coach and Staff Training	Year 1, Month 2	Ongoing
Class Sites Selected/Rental Contracts Completed/Access to Class Sites Obtained	Year 1, Month 2	Ongoing As Needed
Initial Outreach to Service Population	Year 1, Month 3	Ongoing
Participant Recruitment and Enrollment	Year 1, Month 3	Ongoing
DPP Classes	Year 1, Month 3	Year 5, Month 12
CDC, CMS, and FQHC Reporting	Year 1, Month 3	Ongoing
Quarterly SSDPC Leadership Meeting	Year 1, Month 4	Year 5, Month 12
FQHC's Additional A1C Blood Test	Year 1, Month 5	Ongoing
Diabetes Awareness Media Outreach Program - Design	Year 1, Month 12	Year 2, Month 6
Design and conduct a comprehensive study of the short-term health impacts on the patient who take DPP vs. a controlled group who did not to determine the health care economics of the program	Year 2, Month 1	Year 5, Month 6
Retention Analysis and Recommendations	Year 2, Month 6	Annually
Diabetes Awareness Media Outreach Program – Implementation	Year 2, Month 6	Ongoing
Retention Incentives Program – Definition	Year 2, Month 6	Year 2, Month 9
Retention Incentives Program – Implementation	Year 3, Month 1	Ongoing
Hire and Train Program Manager	Year 4, Month 1	Year 4, Month 3
Hire and Train Additional Engagement Manager	Year 5, Month 1	Year 5, Month 3
Analyze and report final program outcomes	Year 5, Month 6	Year 5, Month 12

## 15. Budget

### 1. Annual budgets across the proposal

HTC Budget - FMC 11172021 v3\_15 was submitted with original.

### 2. Number of Individuals Served

Please project the number of individuals that will be served in each year of funding.

Year 1 Individuals

Served **560**

Year 2 Individuals

Served **672**

Year 3 Individuals

Served **896**

Year 4 Individuals

Served **1232**

Year 5 Individuals

Served **1792**

Year 6 Individuals

Served **0**

### 3. Alternative Payment Methodologies

None

## 16. Sustainability

Provide your narrative here:

If the healthcare costs that are associated with the incidence of diabetes can be reduced by preventing many at-risk individuals from progressing to a diagnosis over the course of this project, our South Side Diabetes Prevention Collaborative (SSDPC) will have deployed a model that not only is a method for continued successful provision of service to other populations in Chicago and elsewhere in the domain of diabetes prevention but also for how healthcare collaborators can achieve good outcomes in a prevention program for other widespread diseases that are costly to treat once diagnosed, e.g. hypertension.

As noted, a case of full-blown diabetes costs an average of \$16,000 per year to treat. The best practice prevention model behind our DPP program reduces the chance of getting diabetes by 58% overall and 71% for people over 60. This yields the primary long-term benefit of the program for reducing health care costs as at-risk individuals who do not progress to diabetes will not incur the treatment costs. However, the program also has short-term health benefits from the activity and weight loss that were estimated to be \$770 per individual according to an analysis by United Health Care over three years for its members that participated in their DPP program. Our goal is to reduce the cost of the program to be less than these short-term benefits. If achieved, that will give the program a net positive rate of return in the short-term—to say nothing of the huge long-term savings of avoiding disease progression. By working within the collaboration with the patient referral sources, our FQHC partners, First Mile Care will be able to measure these short-term impacts on the patients who take the program versus those who do not (a ready control group that can be normed for analysis) in order to quite plausibly calculate the health care economic benefits.

The approach to DPP we are proposing is focused on using variable program costs whenever possible versus fixed costs. Over time, this saves money and increases economic sustainability. Variable deployment of our greatest program cost, labor, is both economically prudent and possible. Experience has shown that the demand for program services is uneven throughout the day and week but relatively predictable once targeted participant recruitment has been successfully implemented. It is also programmatically possible by drawing on coaching and recruitment staff

who desire flexible, part-time employment so they can meet other life commitments. By the same token, renting highly variable program locations in the community only on an as-needed basis not only makes the program more responsive to participant needs but avoids the considerable costs of owned or leased premises that might stand idle for much of the day or week.

So instead, we will be renting meeting spaces only when, where, and if they are needed. This cuts program overhead costs, making sustainability more achievable, yet thanks to many small rent payments to community institutions with spare capacity many times during the week also helps sustain them.

The initial months of program implementation will be crucial for establishing the most economical yet also highly effective cost points for program delivery. Inevitably, the labor costs involved in conducting initial outreach to potential participants are bound to be high as we build the initial program prospect registry. During the pilot we will be testing several alternate approaches to recruitment to lower the costs of the outreach process. Costs are bound to decline later as we benefit from having acquired identification data for prospects who aren't ready to commit to services when first approached but may be willing to do so later. We do expect that the per person cost of securing an enrollment from a qualified prospect who is likely to both commit to and complete the program successfully will decline after the first year of the project.

When we successfully negotiate insurance contracts with all funders including Medicare Advantage and other private payers we plan to achieve substantial cost recovery in Year 4.

After success is achieved in this first, fairly modest, neighborhood-specific program implementation, we will seek to expand post-project, to other Chicago neighborhoods and to persuade other large health systems that our prevention activity for diabetes prevention is a fiscally prudent benefit to offer their policy holders. This would spread the overheads further lowering the cost per person.

A core problem we anticipate is that perhaps as many as 40% of the people we anticipate we will be serving will have no billable health insurance. While we will serve them from project funds, there will be no insurer cost recovery and continued financial support will be required for us to be able to serve them after the five-year grant expires. We will work as a collaborative to seek additional funding based on our success for the people without insurance. For the 60% who are insured, we will add billing capability and begin billing for their participation. Our intent is not to leave people out who don't have insurance, rather to demonstrate sustainability by billing for those who have it.

*Summary.* Type 2 diabetes is preventable. The program for diabetes prevention is proven to reduce the risk by up to 70% for people over 60 and has additional benefits in lowering the overall health care costs. This collaboration builds on the success of the 5 FQHC's who are already improving the health of the South Side population. This adds a critical diabetes prevention program. Diabetes costs \$16,000/ per year for life to manage. Our goal is to stop that from ever happening. We also foresee quantifying the short-term health care savings that will essentially pay for the program in the short-term while creating the longer-term reduction in diabetes. This will improve the life of the people we touch and lower the costs of healthcare in the state of Illinois.

Exhibit 1



November 16, 2021

Karl Ronn  
First Mile Care  
3000 Sand Hill Road, Bldg 3  
Menlo Park, CA 94025

Dear Karl,

We are delighted to be part of the new South Side Diabetes Prevention Collaborative (SSDPC). As part of the existing Population Health Collaborative, we have come together to improve the health of the 100,000 people we serve.

Preventing type 2 diabetes is a major priority for us. Diabetes and the diseases that follow like chronic kidney disease are devastating our communities. This new collaborative will allow all of the people we serve to be offered First Mile Care's CDC recognized Diabetes Prevention Program (DPP). The collaboration will build the sustainable capability to fight diabetes in our communities.

We support the grant application being led by First Mile Care. Once the grant is issued, we will sign the necessary legal agreements to make the collaborative successful.

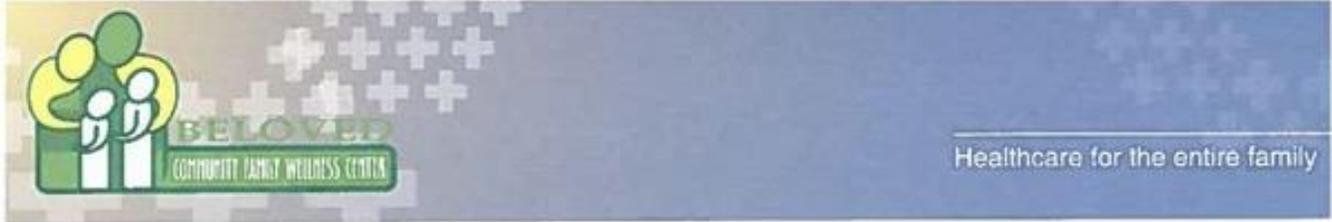
Sincerely,

A handwritten signature in blue ink, appearing to read "KB", is written over a black rectangular redaction box.

Kenneth Burnett  
CEO  
Christian Community Health Center

*where everyone is welcome*

9718 South Halsted Street | Chicago, Illinois 60628 | 773 233 4100 | [www.cche-online.org](http://www.cche-online.org)



November 16, 2021

Karl Ronn  
First Mile Care  
3000 Sand Hill Road, Bldg 3  
Menlo Park, CA 94025

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Sincerely,

  
Margie N. Johnson, MS  
Chief Executive Officer  
Beloved Community Family Wellness Center

Phone: (773) 651-3629 + Fax: (773) 651-9268

Beloved Community Family Wellness Center + 6821 S. Halsted St. + Chicago, Illinois 60621

Barrett Hatches, PhD  
Chicago Family Health Center  
9119 S. Exchange  
Chicago, Illinois 60617



November 16, 2021

Karl Ronn  
First Mile Care  
3000 Sand Hill Road, Bldg 3  
Menlo Park, CA 94025

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We support the grant application being led by First Mile Care. Once the grant is issued, we will sign the necessary legal agreements to make the collaborative successful.

Sincerely,



Barrett Hatches, PhD  
Chief Executive Officer

9119 South Exchange Avenue • Chicago, Illinois 60617  
(773) 768-5000

[www.chicagofamilyhealth.org](http://www.chicagofamilyhealth.org)



## Family Christian Health Center

31 W. 155<sup>th</sup> Street, Harvey, IL 60426 | Ph (708) 596-5177, Fx (708) 339-3583 | [www.familychc.com](http://www.familychc.com)

November 16, 2021

Karl Ronn  
First Mile Care  
3000 Sand Hill Road, Bldg 3  
Menlo Park, CA 94025

Dear Karl,

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Preventing type 2 diabetes is a major priority for us. Diabetes and the diseases that follow like chronic kidney disease are devastating our communities. This new collaborative will allow all of the people we serve to be offered First Mile Care's CDC recognized Diabetes Prevention Program (DPP). The collaboration will build the sustainable capability to fight diabetes in our communities.

We support the grant application being led by First Mile Care. Once the grant is issued, we will sign the necessary legal agreements to make the collaborative successful.

Sincerely,

A black rectangular box redacting the signature of Dr. Lisa Green.

Dr. Lisa Green, MPH  
CEO & Co-Founder



TCA Health Inc. | 1029 E. 130<sup>th</sup> Street, Chicago, IL 60628 | Tel. (773) 995-6300 Fax (773) 995-7985

November 17, 2021

Karl Ronn  
First Mile Care  
3000 Sand Hill Road, Bldg 3  
Menlo Park, CA 94025

Dear Karl:

We are delighted to be part of the new South Side Diabetes Prevention Collaborative (SSDPC). As part of the existing Population Health Collaborative, we have come together to improve the health of the 100,000 people we serve.

Preventing type 2 diabetes is a major priority for us. Diabetes and the diseases that follow like chronic kidney disease are devastating our communities. This new collaborative will allow all of the people we serve to be offered First Mile Care’s CDC recognized Diabetes Prevention Program (DPP). The collaboration will build the sustainable capability to fight diabetes in our communities.

The mission of TCA Health, Inc. is to improve health outcomes by providing high-quality, barrier-free, personalized health care for the entire family. We are dedicated to improving health outcomes for individuals and families by providing and connecting them with services that enhances and improves quality of life. As a Federally Qualified Health Center serving the southside of Chicago for more than 50 years, TCA Health values the Population Health Collaborative as we actively work to improve health outcomes in underserved communities in Chicago.

We support the grant application being led by First Mile Care. Once the grant is issued, we will sign the necessary legal agreements to make the collaborative successful.

Sincerely,

Veronica Clarke  
President and Chief Executive Officer  
TCA Health, Inc.

TCA Health, Inc. - NFP  
1029 E. 130<sup>th</sup> Street,  
Chicago, IL 60628  
773-995-6300

TCA Health- Chatham  
8425 Cottage Grove, Ave.,  
Chicago, IL 60619  
773-846-3000

Carver Military Academy  
School Health Care  
13100 S. Doty Road,  
Chicago, IL 60627  
773-535-5357

Maternal & Child Health  
Center- WIC  
1106 W. 79<sup>th</sup> Street,  
Chicago, IL 60620  
773-488-3048

South Shore Nutrition  
Center- WIC  
1802 E. 71<sup>st</sup> Street,  
Chicago, IL 60649  
773-363-2500



1200 Brickell Avenue | Suite 1950

Miami, Florida, 33146

[www.capgenus.com](http://www.capgenus.com)

Atlanta | Chicago | Houston | Washington DC

November 15, 2021

Dear Health Transformation Collaborative

Re: South Side Diabetes Prevention Collaborative (SSDPC) – Letter of support

It is my pleasure to write a letter of support of the proposal of First Mile Care and five South Side Federally Qualified Health Centers -FQHCs (Beloved Community Family Wellness Center, Chicago Family Health Center, Christian Community Health Center, Family Christian Health Center, and TCA Health, Inc.) in their application for the South Side Diabetes Prevention Collaborative (SSDPC).

Capgenus, a Black-owned management consulting and analytics firm, has served as the lead consulting, clinical design, and analysis firm for the five South Side Federally Qualified Health Centers -FQHCs for the past 3 years. We have been the lead architects for the Population Health Collaborative (PHC) model and analysis plan for the Diabetes Prevention efforts and planned endocrinology focus on specialty care. We have provided consulting services across Chicago for the last seven years and know that diabetes greatly affects our communities. In fact, Dr. Joseph West, Founder of Capgenus, was the lead Principal Investigator for the Lawndale Diabetes Project at Mount Sinai Hospital, and the Sinai Urban Health Institute (SUHI). A ground-breaking community-based initiative funded by Blue Cross and Blue Shield of Illinois (BCBSIL) and the National Institutes for Health (NIH).

The South Side Diabetes Prevention Collaborative (SSDPC) collaborative looks to provide in person coaching, education, counseling, and support to pre diabetic participants on the south side. This collaboration only builds on the success of the five participating FQHC's who are already improving the health in the community on the South Side.

Therefore, I fully support the efforts of First Mile Care and the collaborating five Southside Federally Qualified Health Centers FQHCs (Beloved Community Family Wellness Center, Chicago Family Health Center, Christian Community Health Center, Family Christian Health Center, and TCA Health, Inc.) in their application for the South Side Diabetes Prevention Collaborative (SSDPC). A diabetes prevention program will not only improve the quality of life and health outcomes of the people participating in the program, but it will over time lower healthcare costs in the state of Illinois by being proactive to this chronic disease instead of reactive.

Sincerely,

A solid black rectangular box redacting the signature of the sender.

Founder and Managing Director Capgenus  
**Valued Insight. Customized Solutions.**



PCG Consulting Group  
www.pcgintl.com

November 15, 2021

Dear Health Transformation Collaborative,

Re: South Side Diabetes Prevention Collaborative (SSDPC) – Letter of support

It is my pleasure to write a letter of support of the proposal of First Mile Care and five South Side Federally Qualified Health Centers -FQHCs (Beloved Community Family Wellness Center, Chicago Family Health Center, Christian Community Health Center, Family Christian Health Center, and TCA Health, Inc.) in their application for the South Side Diabetes Prevention Collaborative (SSDPC).

As an employer on the south side and south suburbs, I know that diabetes greatly affects the communities which I represent. The South Side Diabetes Prevention Collaborative (SSDPC) collaborative looks to provide in person coaching, education, counseling, and support to pre diabetic participants on the south side. This collaboration only builds on the success of the five participating FQHC's who are already improving the health in the community on the South Side.

Therefore, I fully support the efforts of First Mile Care and the collaborating five Southside Federally Qualified Health Centers FQHCs (Beloved Community Family Wellness Center, Chicago Family Health Center, Christian Community Health Center, Family Christian Health Center, and TCA Health, Inc.) in their application for the South Side Diabetes Prevention Collaborative (SSDPC). A diabetes prevention program will not only improve the quality of life and health outcomes of the people participating in the program, but it will over time lower healthcare costs in the state of Illinois by being proactive to this chronic disease instead of reactive.

Sincerely,

A redacted signature consisting of a black rectangular box covering the name and handwritten signature of the sender.

T. Tom Numbere Jr.  
PCG Consulting Group  
President/CEO  
312 343 5265

*"Guiding clients through the maze of a complicated world by knowledge, experience, and dedication"*

Exhibit 2

**DISTRICT OFFICE:**  
1234 W. 95<sup>TH</sup> STREET  
CHICAGO, ILLINOIS 60643  
PHONE: 773-445-9700

**SPRINGFIELD OFFICE:**  
248-E STRATTON BUILDING  
SPRINGFIELD, ILLINOIS 62706  
PHONE: 217-782-0010



**JUSTIN SLAUGHTER**  
STATE REPRESENTATIVE • 27TH DISTRICT

**CHAIRPERSON**  
• JUDICIARY - CRIMINAL

**VICE-CHAIRPERSON**  
• STATE GOVERNMENT  
• ADMINISTRATION

**COMMITTEES**  
• APPROPRIATIONS  
• HIGHER EDUCATION  
• PUBLIC UTILITIES  
• INTERNATIONAL TRADE  
& COMMERCE

November 15, 2021

Dear Health Transformation Collaborative,

Re: South Side Diabetes Prevention Collaborative (SSDPC) – Letter of support

It is my pleasure to write a letter of support of the proposal of First Mile Care and five South Side Federally Qualified Health Centers -FQHCs (Beloved Community Family Wellness Center, Chicago Family Health Center, Christian Community Health Center, Family Christian Health Center, and TCA Health, Inc.) in their application for the South Side Diabetes Prevention Collaborative (SSDPC).

As a state Representative on the South Side and south suburbs, I know that diabetes greatly affects the communities I represent. The South Side Diabetes Prevention Collaborative (SSDPC) collaborative looks to provide in-person coaching, education, counseling, and support to pre-diabetic participants on the South Side. This collaboration only builds on the success of the five participating FQHCs who are already improving the health in the community on the South Side.

Therefore, I fully support the efforts of First Mile Care and the collaborating five South Side Federally Qualified Health Centers FQHCs (Beloved Community Family Wellness Center, Chicago Family Health Center, Christian Community Health Center, Family Christian Health Center, and TCA Health, Inc.) in their application for the South Side Diabetes Prevention Collaborative (SSDPC). A diabetes prevention program will not only improve the quality of life and health outcomes of the people participating in the program, but it will lower healthcare costs in the state of Illinois by being proactive to this chronic disease instead of reactive.

Sincerely,



IL State Representative Justin Slaughter - 27th District

SOYBEAN INKS

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## REDUCTION IN THE INCIDENCE OF TYPE 2 DIABETES WITH LIFESTYLE INTERVENTION OR METFORMIN

DIABETES PREVENTION PROGRAM RESEARCH GROUP\*

### ABSTRACT

**Background** Type 2 diabetes affects approximately 8 percent of adults in the United States. Some risk factors — elevated plasma glucose concentrations in the fasting state and after an oral glucose load, overweight, and a sedentary lifestyle — are potentially reversible. We hypothesized that modifying these factors with a lifestyle-intervention program or the administration of metformin would prevent or delay the development of diabetes.

**Methods** We randomly assigned 3234 nondiabetic persons with elevated fasting and post-load plasma glucose concentrations to placebo, metformin (850 mg twice daily), or a lifestyle-modification program with the goals of at least a 7 percent weight loss and at least 150 minutes of physical activity per week. The mean age of the participants was 51 years, and the mean body-mass index (the weight in kilograms divided by the square of the height in meters) was 34.0; 68 percent were women, and 45 percent were members of minority groups.

**Results** The average follow-up was 2.8 years. The incidence of diabetes was 11.0, 7.8, and 4.8 cases per 100 person-years in the placebo, metformin, and lifestyle groups, respectively. The lifestyle intervention reduced the incidence by 58 percent (95 percent confidence interval, 48 to 66 percent) and metformin by 31 percent (95 percent confidence interval, 17 to 43 percent), as compared with placebo; the lifestyle intervention was significantly more effective than metformin. To prevent one case of diabetes during a period of three years, 6.9 persons would have to participate in the lifestyle-intervention program, and 13.9 would have to receive metformin.

**Conclusions** Lifestyle changes and treatment with metformin both reduced the incidence of diabetes in persons at high risk. The lifestyle intervention was more effective than metformin. (N Engl J Med 2002; 346:393-403.)

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**T**YPE 2 diabetes mellitus, formerly called non-insulin-dependent diabetes mellitus, is a serious, costly disease affecting approximately 8 percent of adults in the United States.<sup>1</sup> Treatment prevents some of its devastating complications<sup>2,3</sup> but does not usually restore normoglycemia or eliminate all the adverse consequences. The diagnosis is often delayed until complications are present.<sup>4</sup> Since current methods of treating diabetes remain inadequate, prevention is preferable. The hypothesis that type 2 diabetes is preventable<sup>5,6</sup> is supported by observational studies and two clinical trials of diet, exercise, or both in persons at high risk for the disease<sup>7,8</sup> but not by studies of drugs used to treat diabetes.<sup>5</sup>

The validity of generalizing the results of previous prevention studies is uncertain.<sup>9</sup> Interventions that work in some societies may not work in others, because social, economic, and cultural forces influence diet and exercise. This is a special concern in the United States, where there is great regional and ethnic diversity in lifestyle patterns and where diabetes is especially frequent in certain racial and ethnic groups, including American Indians, Hispanics, African Americans, Asians, and Pacific Islanders.<sup>10</sup>

The Diabetes Prevention Program Research Group conducted a large, randomized clinical trial involving adults in the United States who were at high risk for the development of type 2 diabetes. The study was designed to answer the following primary questions: Does a lifestyle intervention or treatment with

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\*The members of the Diabetes Prevention Program Research Group are listed in the Appendix.

metformin, a biguanide antihyperglycemic agent, prevent or delay the onset of diabetes? Do these two interventions differ in effectiveness? Does their effectiveness differ according to age, sex, or race or ethnic group?

## METHODS

We conducted a clinical trial involving persons at 27 centers who were at high risk for diabetes. The methods have been described in detail elsewhere,<sup>6</sup> and the protocol is available at <http://www.bsc.gwu.edu/dpp>. The institutional review board at each center approved the protocol, and all participants gave written informed consent.

### Participants

Eligibility criteria included an age of at least 25 years, a body-mass index (the weight in kilograms divided by the square of the height in meters) of 24 or higher (22 or higher in Asians), and a plasma glucose concentration of 95 to 125 mg per deciliter (5.3 to 6.9 mmol per liter) in the fasting state ( $\leq 125$  mg per deciliter in the American Indian clinics) and 140 to 199 mg per deciliter (7.8 to 11.0 mmol per liter) two hours after a 75-g oral glucose load. These concentrations are elevated but are not diagnostic of diabetes according to the 1997 criteria of the American Diabetes Association.<sup>11</sup> Before June 1997, the criterion for plasma glucose in the fasting state was 100 to 139 mg per deciliter (5.6 to 7.7 mmol per liter), or  $\leq 139$  mg per deciliter in the American Indian clinics. Eligible persons were excluded if they were taking medicines known to alter glucose tolerance or if they had illnesses that could seriously reduce their life expectancy or their ability to participate in the trial. Recruitment was designed to enroll approximately half the participants from racial or ethnic minority groups. A four-step screening and recruitment process was developed to identify eligible participants.<sup>6,12,13</sup>

### Interventions

Eligible participants were randomly assigned to one of three interventions: standard lifestyle recommendations plus metformin (Glucophage) at a dose of 850 mg twice daily, standard lifestyle recommendations plus placebo twice daily, or an intensive program of lifestyle modification. The study initially included a fourth intervention, troglitazone, which was discontinued in 1998 because of the drug's potential liver toxicity.<sup>6</sup> The results in the troglitazone group are not reported here.

Treatment with metformin was initiated at a dose of 850 mg taken orally once a day, with placebo tablets also given once a day initially. At one month, the dose of metformin was increased to 850 mg twice daily, unless gastrointestinal symptoms warranted a longer titration period. The initiation of treatment with half a tablet was optional. Adherence to the treatment regimen was assessed quarterly on the basis of pill counts and structured interviews. The standard lifestyle recommendations for the medication groups were provided in the form of written information and in an annual 20-to-30-minute individual session that emphasized the importance of a healthy lifestyle. Participants were encouraged to follow the Food Guide Pyramid<sup>14</sup> and the equivalent of a National Cholesterol Education Program Step 1 diet,<sup>15</sup> to reduce their weight, and to increase their physical activity.

The goals for the participants assigned to the intensive lifestyle intervention were to achieve and maintain a weight reduction of at least 7 percent of initial body weight through a healthy low-calorie, low-fat diet and to engage in physical activity of moderate intensity, such as brisk walking, for at least 150 minutes per week. A 16-lesson curriculum covering diet, exercise, and behavior modification was designed to help the participants achieve these goals. The curriculum, taught by case managers on a one-to-one basis

during the first 24 weeks after enrollment, was flexible, culturally sensitive, and individualized. Subsequent individual sessions (usually monthly) and group sessions with the case managers were designed to reinforce the behavioral changes.

### Outcome Measures

The primary outcome was diabetes, diagnosed on the basis of an annual oral glucose-tolerance test or a semiannual fasting plasma glucose test, according to the 1997 criteria of the American Diabetes Association: a value for plasma glucose of 126 mg per deciliter (7.0 mmol per liter) or higher in the fasting state or 200 mg per deciliter (11.1 mmol per liter) or higher two hours after a 75-g oral glucose load.<sup>11</sup> In addition to the semiannual measurements, fasting plasma glucose was measured if symptoms suggestive of diabetes developed. The diagnosis required confirmation by a second test, usually within six weeks, according to the same criteria. If diabetes was diagnosed, the participants and their physicians were informed and glucose-tolerance tests were discontinued, but fasting plasma glucose was measured every six months, with glycosylated hemoglobin measured annually. As long as the fasting plasma glucose concentration was less than 140 mg per deciliter, participants were asked to monitor their blood glucose and to continue their assigned study treatment. If the fasting plasma glucose concentration reached or exceeded 140 mg per deciliter, the study medication was discontinued and the participant was referred to his or her physician for treatment. Measurements of glucose and glycosylated hemoglobin ( $HbA_{1c}$ ) were performed centrally. All tests were performed without interrupting the assigned treatment, except that placebo or metformin was not taken on the morning of the test. The investigators and the participants were unaware of the results of these measurements and were informed only if the results exceeded the specified threshold for a change in the treatment.

Self-reported levels of leisure physical activity were assessed annually with the Modifiable Activity Questionnaire.<sup>16</sup> The physical-activity level was calculated as the product of the duration and frequency of each activity (in hours per week), weighted by an estimate of the metabolic equivalent of that activity (MET) and summed for all activities performed, with the result expressed as the average MET-hours per week for the previous year. Usual daily caloric intake during the previous year, including calories from fat, carbohydrate, protein, and other nutrients, was assessed at base line and at one year with the use of a modified version of the Block food-frequency questionnaire.<sup>17</sup>

### Statistical Analysis and Early Closure

Random treatment assignments were stratified according to the clinical center. Assignments to metformin and placebo were double-blinded. The study design and analysis followed the intention-to-treat principle. Nominal (unadjusted) P values and confidence intervals are reported.

The blinded treatment phase was terminated one year early, in May 2001, on the advice of the data monitoring board, on the basis of data obtained through March 31, 2001, the closing date for this report. By then, we had obtained evidence of efficacy on the basis of 65 percent of the planned person-years of observation. To maintain a type I error level of 0.05 for significance in pairwise comparisons of the risk of diabetes between groups, with adjustment for repeated interim analyses, the group-sequential log-rank test<sup>18</sup> required a P value of less than 0.0159. For pairwise comparisons of other outcomes, a Bonferroni-adjusted criterion of  $P < 0.0167$  was used. The study design provided 90 percent power to detect a 33 percent reduction from an incidence of 6.5 cases of diabetes per 100 person-years, with a 10 percent rate of loss to follow-up per year.

The time to the outcome was assessed with the use of life-table methods.<sup>19</sup> Modified product-limit curves for the cumulative incidence of diabetes were compared with the use of the log-rank test. The estimated cumulative incidence at three years and the

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Greenwood estimate of the standard error were used to calculate the number of persons who would need to be treated in order to prevent one case of confirmed diabetes during a period of three years and the associated 95 percent confidence interval. Risk reduction, heterogeneity among strata, and interactions between treatment assignments and covariates were assessed by proportional-hazards regression. Fixed-effects models with the assumption of normally distributed errors<sup>20</sup> were used to assess differences over time in body weight and plasma glucose and glycosylated hemoglobin values among the three groups.

RESULTS

Study Cohort and Follow-up

From 1996 to 1999, we randomly assigned 3234 study participants to one of the three interventions (1082 to placebo, 1073 to metformin, and 1079 to the intensive lifestyle intervention). Base-line characteristics, including all measured risk factors for diabetes, were similar among the three study groups (Table 1).<sup>12</sup> The participants were followed for an av-

erage of 2.8 years (range, 1.8 to 4.6). At the close of the study, 99.6 percent of the participants were alive, of whom 92.5 percent had attended a scheduled visit within the previous five months.

Adherence to Interventions

Fifty percent of the participants in the lifestyle-intervention group had achieved the goal of weight loss of 7 percent or more by the end of the curriculum (at 24 weeks), and 38 percent had a weight loss of at least 7 percent at the time of the most recent visit; the proportion of participants who met the goal of at least 150 minutes of physical activity per week (assessed on the basis of logs kept by the participants) was 74 percent at 24 weeks and 58 percent at the most recent visit. Dietary change was assessed only at one year. Daily energy intake decreased by a mean ( $\pm$ SE) of  $249 \pm 27$  kcal in the placebo group,  $296 \pm 23$  kcal in the metformin group, and  $450 \pm 26$

TABLE 1. BASE-LINE CHARACTERISTICS OF THE STUDY PARTICIPANTS.\*

CHARACTERISTIC	OVERALL (N=3234)	PLACEBO (N=1082)	METFORMIN (N=1073)	LIFESTYLE (N=1079)
Sex — no. (%)				
Male	1043 (32.3)	335 (31.0)	363 (33.8)	345 (32.0)
Female	2191 (67.7)	747 (69.0)	710 (66.2)	734 (68.0)
Race or ethnic group — no. (%)				
White	1768 (54.7)	586 (54.2)	602 (56.1)	580 (53.8)
African American	645 (19.9)	220 (20.3)	221 (20.6)	204 (18.9)
Hispanic	508 (15.7)	168 (15.5)	162 (15.1)	178 (16.5)
American Indian	171 (5.3)	59 (5.5)	52 (4.8)	60 (5.6)
Asian†	142 (4.4)	49 (4.5)	36 (3.4)	57 (5.3)
Family history of diabetes — no. (%)	2243 (69.4)	758 (70.1)	733 (68.3)	752 (69.8)‡
History of gestational diabetes — no. of women (%)	353 (16.1)	122 (16.3)	111 (15.7)‡	120 (16.3)
Age — yr	50.6 $\pm$ 10.7	50.3 $\pm$ 10.4	50.9 $\pm$ 10.3	50.6 $\pm$ 11.3
Weight — kg	94.2 $\pm$ 20.3	94.3 $\pm$ 20.2	94.3 $\pm$ 19.9	94.1 $\pm$ 20.8
Body-mass index	34.0 $\pm$ 6.7	34.2 $\pm$ 6.7	33.9 $\pm$ 6.6	33.9 $\pm$ 6.8
Waist circumference — cm	105.1 $\pm$ 14.5	105.2 $\pm$ 14.3	104.9 $\pm$ 14.4	105.1 $\pm$ 14.8
Waist-to-hip ratio	0.92 $\pm$ 0.09	0.93 $\pm$ 0.09	0.93 $\pm$ 0.09	0.92 $\pm$ 0.08
Plasma glucose — mg/dl§				
In the fasting state	106.5 $\pm$ 8.3	106.7 $\pm$ 8.4	106.5 $\pm$ 8.5	106.3 $\pm$ 8.1
Two hours after an oral glucose load	164.6 $\pm$ 17.0	164.5 $\pm$ 17.1	165.1 $\pm$ 17.2	164.4 $\pm$ 16.8
Glycosylated hemoglobin — %	5.91 $\pm$ 0.50	5.91 $\pm$ 0.50	5.91 $\pm$ 0.50	5.91 $\pm$ 0.51
Leisure physical activity — MET-hr/wk¶	16.3 $\pm$ 25.8	17.0 $\pm$ 29.0	16.4 $\pm$ 25.9	15.5 $\pm$ 22.1

\*Plus-minus values are means  $\pm$ SD.

†Twenty Pacific Islanders were included in this category.

‡Information was not available for one participant.

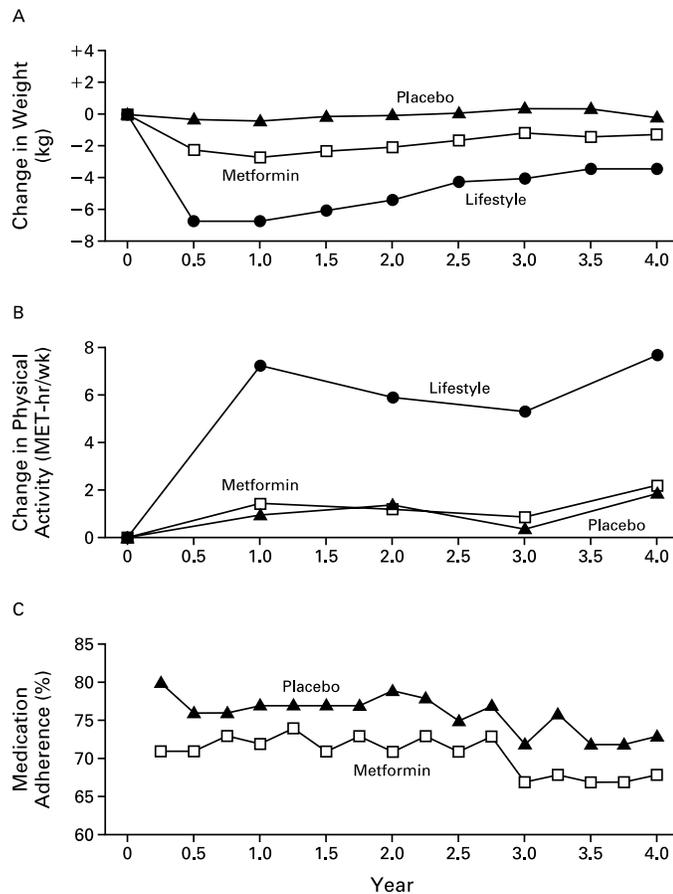
§To convert the values for glucose to millimoles per liter, multiply by 0.05551.

¶Data are based on responses to the Modifiable Activity Questionnaire.<sup>16</sup> MET denotes metabolic equivalent. MET-hours represent the average amount of time engaged in specified physical activities multiplied by the MET value of each activity.

kcal in the lifestyle-intervention group ( $P < 0.001$ ). Average fat intake, which was 34.1 percent of total calories at base line, decreased by  $0.8 \pm 0.2$  percent in the placebo and metformin groups and by  $6.6 \pm 0.2$  percent in the lifestyle-intervention group ( $P < 0.001$ ). The proportion of participants who took at least 80 percent of the prescribed dose of the study medication was slightly higher in the placebo group than in the metformin group (77 percent vs. 72 percent,  $P < 0.001$ ). Ninety-seven percent of the partic-

ipants taking placebo and 84 percent of those taking metformin were given the full dose of one tablet (850 mg in the case of metformin) twice a day; the remainder were given one tablet a day to limit side effects.

Changes in weight and leisure physical activity in all three groups and adherence to the medication regimen in the metformin and placebo groups are shown in Figure 1. Participants assigned to the lifestyle intervention had much greater weight loss and a great-



**Figure 1.** Changes in Body Weight (Panel A) and Leisure Physical Activity (Panel B) and Adherence to Medication Regimen (Panel C) According to Study Group.

Each data point represents the mean value for all participants examined at that time. The number of participants decreased over time because of the variable length of time that persons were in the study. For example, data on weight were available for 3085 persons at 0.5 year, 3064 at 1 year, 2887 at 2 years, and 1510 at 3 years. Changes in weight and leisure physical activity over time differed significantly among the treatment groups ( $P < 0.001$  for each comparison).

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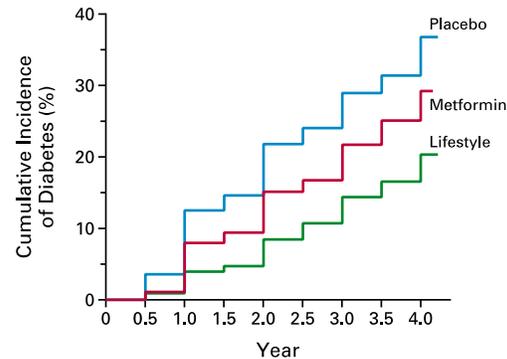
er increase in leisure physical activity than did participants assigned to receive metformin or placebo. The average weight loss was 0.1, 2.1, and 5.6 kg in the placebo, metformin, and lifestyle-intervention groups, respectively ( $P < 0.001$ ).

**Incidence of Diabetes**

The cumulative incidence of diabetes was lower in the metformin and lifestyle-intervention groups than in the placebo group throughout the follow-up period (Fig. 2). The crude incidence was 11.0, 7.8, and 4.8 cases per 100 person-years for the placebo, metformin, and lifestyle-intervention groups, respectively (Table 2). The incidence of diabetes was 58 percent lower (95 percent confidence interval, 48 to 66 percent) in the lifestyle-intervention group and 31 percent lower (95 percent confidence interval, 17 to 43 percent) in the metformin group than in the placebo group. The incidence of diabetes was 39 percent lower (95 percent confidence interval, 24 to 51 percent) in the lifestyle-intervention group than in the metformin group. The results of all three pairwise group comparisons were statistically significant by the group-sequential log-rank test. None of these results were materially affected by adjustment for base-line characteristics. The estimated cumulative incidence of diabetes at three years was 28.9 percent, 21.7 percent, and 14.4 percent in the placebo, metformin, and lifestyle-intervention groups, respectively. On the basis of these rates, the estimated number of persons who would need to be treated for three years to prevent one case of diabetes during this period is 6.9 (95 percent confidence interval, 5.4 to 9.5) for the lifestyle intervention and 13.9 (95 percent confidence interval, 8.7 to 33.9) for metformin.

**Treatment Effects among Subgroups**

Incidence rates and risk reductions within subgroups of participants and the results of tests of the homogeneity of risk reduction among subgroups are shown in Table 2; 95 percent confidence intervals for the subgroup data indicate the precision of the risk-reduction estimate for each stratum. The study had inadequate power to assess the significance of effects within the subgroups, nor were such tests planned. Significant heterogeneity indicates that treatment effects differed according to the values of the covariates. Treatment effects did not differ significantly according either to sex or to race or ethnic group (Table 2). The lifestyle intervention was highly effective in all subgroups. Its effect was significantly greater among persons with lower base-line glucose concentrations two hours after a glucose load than among those with higher base-line glucose values. The effect of metformin was less with a lower body-mass index or a lower fasting glucose concentration than with higher



**Figure 2.** Cumulative Incidence of Diabetes According to Study Group.

The diagnosis of diabetes was based on the criteria of the American Diabetes Association.<sup>11</sup> The incidence of diabetes differed significantly among the three groups ( $P < 0.001$  for each comparison).

values for those variables. Neither interaction was explained by the other variable or by age. The advantage of the lifestyle intervention over metformin was greater in older persons and those with a lower body-mass index than in younger persons and those with a higher body-mass index.

**Glycemic Changes**

In the first year, there was a similar reduction in the mean fasting plasma glucose values in the metformin and lifestyle-intervention groups, whereas the values rose in the placebo group (Fig. 3). The values rose in parallel in all three groups in subsequent years. There was a similar temporal pattern in the values for glycosylated hemoglobin, except that the values in the metformin group were in between those in the lifestyle-intervention and placebo groups. Figure 4 shows the percentage of participants who had normal glucose concentrations (fasting values, post-load values, and both) at each annual examination. Metformin and the lifestyle intervention were similarly effective in restoring normal fasting glucose values, but the lifestyle intervention was more effective in restoring normal post-load glucose values.

**Adverse Events**

The rate of gastrointestinal symptoms was highest in the metformin group, and the rate of musculoskeletal symptoms was highest in the lifestyle-intervention group (Table 3). Hospitalization and mortality rates were unrelated to treatment. No deaths were attributed to the study intervention.

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TABLE 2. INCIDENCE OF DIABETES.

VARIABLE	NO. OF PARTICIPANTS (%)	INCIDENCE			REDUCTION IN INCIDENCE (95% CI)*		
		PLACEBO	METFORMIN	LIFESTYLE	LIFESTYLE VS. PLACEBO	METFORMIN VS. PLACEBO	LIFESTYLE VS. METFORMIN
		cases/100 person-yr			percent		
Overall	3234 (100)	11.0	7.8	4.8	58 (48 to 66)	31 (17 to 43)	39 (24 to 51)
Age							
25–44 yr	1000 (30.9)	11.6	6.7	6.2	48 (27 to 63)	44 (21 to 60)	8 (–36 to 37)†
45–59 yr	1586 (49.0)	10.8	7.6	4.7	59 (44 to 70)	31 (10 to 46)	41 (18 to 57)†
≥60 yr	648 (20.0)	10.8	9.6	3.1	71 (51 to 83)	11 (–33 to 41)	69 (47 to 82)†
Sex							
Male	1043 (32.3)	12.5	8.1	4.6	65 (49 to 76)	37 (14 to 54)	46 (20 to 63)
Female	2191 (67.7)	10.3	7.6	5.0	54 (40 to 64)	28 (10 to 43)	36 (16 to 51)
Race or ethnic group							
White	1768 (54.7)	10.3	7.8	5.2	51 (35 to 63)	24 (3 to 41)	36 (14 to 52)
African American	645 (19.9)	12.4	7.1	5.1	61 (37 to 76)	44 (16 to 63)	29 (–18 to 58)
Hispanic	508 (15.7)	11.7	8.4	4.2	66 (41 to 80)	31 (–9 to 56)	51 (13 to 72)
American Indian	171 (5.3)	12.9	9.7	4.7	65 (7 to 87)	25 (–72 to 68)	52 (–35 to 83)
Asian‡	142 (4.4)	12.1	7.5	3.8	71 (24 to 89)	38 (–55 to 75)	52 (–46 to 84)
Body-mass index§							
22 to <30	1045 (32.3)	9.0	8.8	3.3	65 (46 to 77)	3 (–36 to 30)†	63 (44 to 76)†
30 to <35	995 (30.8)	8.9	7.6	3.7	61 (40 to 75)	16 (–19 to 41)†	53 (28 to 70)†
≥35	1194 (36.9)	14.3	7.0	7.3	51 (34 to 63)	53 (36 to 65)†	–4 (–47 to 26)†
Plasma glucose¶							
In the fasting state							
95–109 mg/dl	2174 (67.2)	6.4	5.5	2.9	55 (38 to 68)	15 (–12 to 36)†	48 (27 to 63)
110–125 mg/dl**	1060 (32.8)	22.3	12.3	8.8	63 (51 to 72)	48 (33 to 60)†	30 (6 to 48)
Two hours after an oral load							
140–153 mg/dl	1049 (32.4)	7.1	4.3	1.8	76 (58 to 86)†	41 (11 to 61)	59 (27 to 77)
154–172 mg/dl	1103 (34.1)	10.3	6.6	4.4	60 (41 to 72)†	38 (13 to 56)	34 (2 to 56)
173–199 mg/dl	1082 (33.5)	16.1	12.3	8.5	50 (33 to 63)†	26 (3 to 43)	33 (9 to 51)

\*CI denotes confidence interval.

†P<0.05 for the test of heterogeneity across strata. Age, body-mass index, and plasma glucose were analyzed as continuous variables.

‡This category includes 20 Pacific Islanders.

§The eligibility criterion was a body-mass index of at least 22 for Asians and at least 24 for all other persons.

¶To convert the values for glucose to millimoles per liter, multiply by 0.05551.

||This category includes American Indian participants who had a fasting glucose concentration that was less than 95 mg per deciliter, according to the eligibility criteria.<sup>9</sup>

\*\*This category includes 54 participants with a fasting glucose concentration of 126 to 139 mg per deciliter who were enrolled before June 1997<sup>9</sup> when the eligibility criteria were changed to conform to the diagnostic criteria of the American Diabetes Association, published that year.<sup>11</sup>

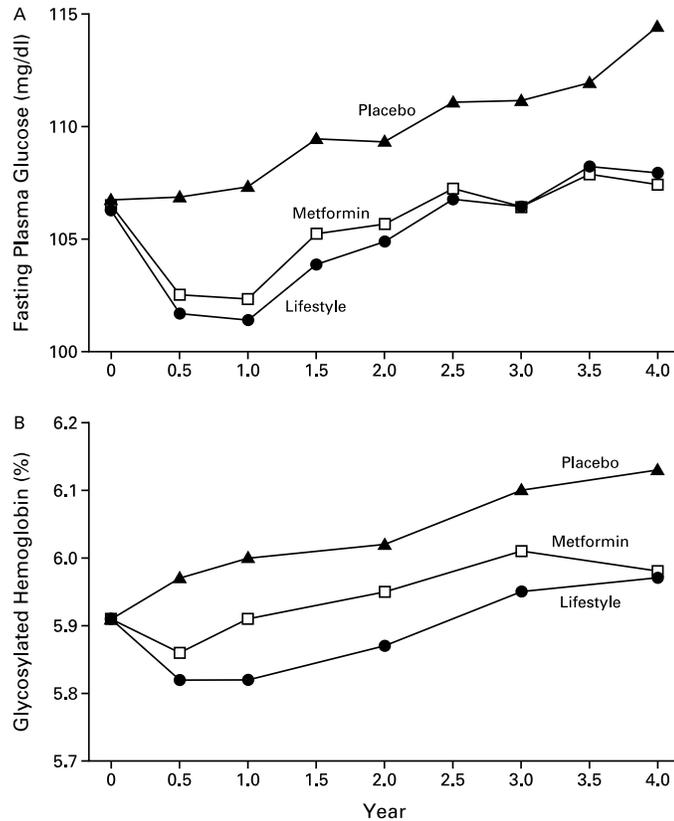
DISCUSSION

Our results support the hypothesis that type 2 diabetes can be prevented or delayed in persons at high risk for the disease. The incidence of diabetes was reduced by 58 percent with the lifestyle intervention and by 31 percent with metformin, as compared with placebo. These effects were similar in men and women and in all racial and ethnic groups. The intensive lifestyle intervention was at least as effective in older participants as it was in younger participants. The results of our study extend previous data showing that lifestyle interventions can reduce the incidence of diabetes<sup>7,8</sup> and demonstrate the applicability of this finding to the ethnically and cul-

turally diverse population of the United States. The risk reduction associated with the lifestyle intervention in our study was the same as that in a study conducted in Finland,<sup>8</sup> and was higher than the reductions associated with diet (31 percent), exercise (46 percent), and diet plus exercise (42 percent) in a study in China.<sup>7</sup>

Our lifestyle intervention was systematic and intensive, with the study participants receiving detailed, individualized counseling. The study, however, was not designed to test the relative contributions of dietary changes, increased physical activity, and weight loss to the reduction in the risk of diabetes, and the effects of these components remain to be determined.

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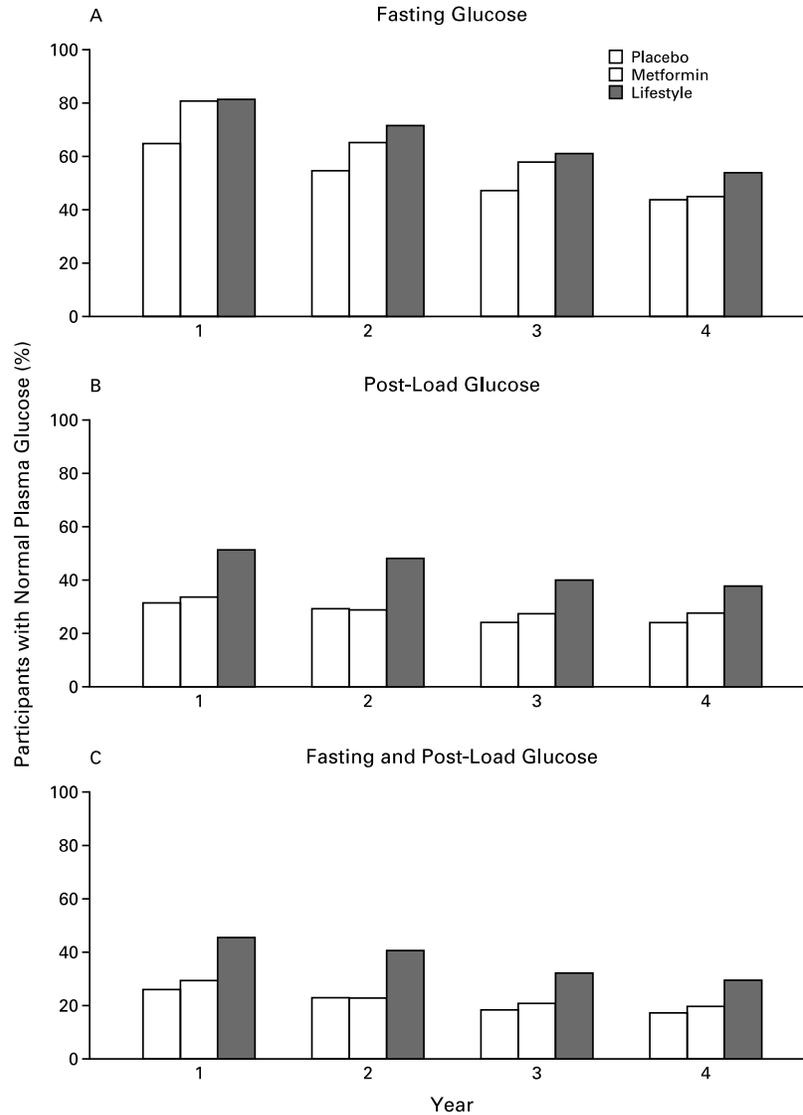
**Figure 3.** Fasting Plasma Glucose Concentrations (Panel A) and Glycosylated Hemoglobin Values (Panel B) According to Study Group. The analysis included all participants, whether or not diabetes had been diagnosed. Changes in fasting glucose values over time in the three groups differed significantly ( $P < 0.001$ ). Glycosylated hemoglobin values in the three groups differed significantly from 0.5 to 3 years ( $P < 0.001$ ). To convert the values for glucose to millimoles per liter, multiply by 0.05551.

The incidence of diabetes in our placebo group (11.0 cases per 100 person-years) was higher than we had anticipated<sup>6</sup> and was higher than the incidence in observational studies,<sup>21</sup> perhaps owing to the greater frequency of glucose testing or to the selection of persons at higher risk in our study. The incidence of diabetes in the placebo group was similar among racial and ethnic groups despite differences in these subgroups in observational, population-based studies.<sup>10</sup> Racial and ethnic-group differences in the incidence of diabetes were presumably reduced in

our study by the selection of persons who were overweight and had elevated fasting and post-load glucose concentrations — three of the strongest risk factors for diabetes.

Previous studies have not demonstrated that drugs used to treat diabetes are effective for its prevention, perhaps because of small samples and the lack of data on adherence to the prescribed regimens.<sup>5</sup> In contrast, metformin was effective in our study, although less so than the lifestyle intervention. Metformin was less effective in persons with a lower base-line body-

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**Figure 4.** Participants with Normal Plasma Glucose Values, According to Study Group.

Panel A shows the proportions of participants with normal glucose values in the fasting state (<110 mg per deciliter [6.1 mmol per liter]), Panel B the proportions with normal values two hours after an oral glucose load (<140 mg per deciliter [7.8 mmol per liter]), and Panel C the proportions with normal values for both measurements. Persons in whom a diagnosis of diabetes had been made were considered to have abnormal values, regardless of the actual values at the time. By design, no participants had normal post-load glucose values at base line, but base-line fasting glucose values were normal in 67 percent of persons in the placebo group, 67 percent of those in the metformin group, and 68 percent of those in the lifestyle-intervention group. Metformin and lifestyle intervention were similarly effective in restoring normal fasting glucose concentrations, but lifestyle intervention was more effective in restoring normal post-load glucose concentrations.

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TABLE 3. ADVERSE EVENTS.

EVENT	PLACEBO	METFORMIN	LIFESTYLE
Gastrointestinal symptoms (no. of events/100 person-yr)*	30.7	77.8†	12.9†
Musculoskeletal symptoms (no. of events/100 person-yr)‡	21.1	20.0	24.1†
Hospitalization			
One or more admissions (% of participants)	16.1	15.9	15.6
Rate (no. of admissions/100 person-yr)	7.9	8.4	8.0
Median stay (days)	3	3	3
Deaths (no./100 person-yr)	0.16	0.20	0.10

\*Gastrointestinal symptoms included diarrhea, flatulence, nausea, and vomiting.

†P<0.0167 for the comparison with placebo.

‡Most participants with musculoskeletal symptoms had myalgia, arthritis, or arthralgia.

mass index or a lower fasting plasma glucose concentration than in those with higher values for these variables. The reduction in the average fasting plasma glucose concentration was similar in the lifestyle-intervention and metformin groups, but the lifestyle-intervention had a greater effect than metformin on glycosylated hemoglobin, and a larger proportion of participants in the lifestyle-intervention group had normal post-load glucose values at follow-up. These findings are consistent with the observation that metformin suppresses endogenous glucose production, the main determinant of fasting plasma glucose concentrations.<sup>22</sup>

Rates of adverse events, hospitalization, and mortality were similar in the three groups, except that the rate of gastrointestinal symptoms was highest in the metformin group and the rate of musculoskeletal symptoms was highest in the lifestyle-intervention group. Thus, the interventions were safe in addition to being effective.

An estimated 10 million persons in the United States resemble the participants in the Diabetes Prevention Program in terms of age, body-mass index, and glucose concentrations, according to data from the third National Health and Nutrition Examination Survey.<sup>23</sup> If the study's interventions were implemented among these people, there would be a substantial reduction in the incidence of diabetes. Ultimately, the benefits would depend on whether glucose concentrations could be maintained at levels below those that are diagnostic of diabetes and whether the maintenance of these lower levels improved the long-term outcome. These questions should be addressed by continued follow-up of the study participants and by

analysis of the main secondary outcomes — reductions in risk factors for cardiovascular disease, in the proportion of participants with atherosclerosis, and in the proportion with cardiovascular disease, which is the leading cause of death among patients with type 2 diabetes.<sup>24,25</sup>

Optimal approaches to identifying candidates for preventive measures remain to be determined. Although elevation of either the fasting or the post-load glucose concentration strongly predicts diabetes,<sup>26,27</sup> both were required for eligibility in this study. Whether the results would be similar in persons with an isolated elevation of the fasting or post-load glucose concentration or other risk factors for diabetes is likely but unknown.

In summary, our study showed that treatment with metformin and modification of lifestyle were two highly effective means of delaying or preventing type 2 diabetes. The lifestyle intervention was particularly effective, with one case of diabetes prevented per seven persons treated for three years. Thus, it should also be possible to delay or prevent the development of complications, substantially reducing the individual and public health burden of diabetes.

Supported by the National Institutes of Health through the National Institute of Diabetes and Digestive and Kidney Diseases, the Office of Research on Minority Health, the National Institute of Child Health and Human Development, and the National Institute on Aging; the Indian Health Service; the Centers for Disease Control and Prevention; the General Clinical Research Center Program, National Center for Research Resources; the American Diabetes Association; Bristol-Myers Squibb; and Parke-Davis.

Dr. Hamman owns stock in Bristol-Myers Squibb, which sells metformin in the United States.

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APPENDIX

The following investigators were members of the Diabetes Prevention Program Research Group (asterisks indicate principal investigators, and daggers program coordinators): *Pennington Biomedical Research Center* — G.A. Bray,\* I.W. Culbert,† C.M. Champagne, M.D. Crow, L. Dawson, B. Eberhardt, E.L. Greenway, E.G. Guillory, A.A. Hebert, M.L. Jeffers, K. Joyce, B.M. Kennedy, J.C. Lovejoy, S. Mancuso, L.E. Melancon, L.H. Morris, L. Reed, J. Perault, K. Rau, D.H. Ryan, D.A. Sanford, K.G. Smith, L.L. Smith, S.R. Smith, J.A. St. Amant, M. Terry, E. Tucker, R.T. Tulley, P.C. Vicknair, D. Williamson, and J.J. Zachwieja; *University of Chicago* — D.A. Ehrmann,\* M.J. Matulik,† B. Clarke, D.A. Collins, K.B. Czech, C. DeSandro, G. Geiger, S. Grief, B. Harding-Clay, R.M. Hilbrich, D. le Grange, M.R. McCormick, W.L. McNabb, K.S. Polonsky, N.P. Sauter, A.R. Semenske, K.A. Stepp, and J.A. Tobian; *Jefferson Medical College* — P.G. Watson,\* J.T. Mendoza,† K.A. Smith,† J. Caro, B. Goldstein, C. Lark, L. Menefee, L. Murphy, C. Pepe, and J.M. Spandorfer; *University of Miami* — R.B. Goldberg,\* P. Rowe,† J. Calles, P. Casanova, R.P. Donahue, H.J. Florez, A. Giannella, G. Larreal, V. McLymont, J. Mendez, P. O'Hara, J. Ojito, R. Prineas, and P.G. Saab; *The University of Texas Health Science Center* — S.M. Haffner,\* M.G. Montez,† C. Lorenzo, H. Miettinen,

REDUCING THE INCIDENCE OF TYPE 2 DIABETES WITH LIFESTYLE INTERVENTION OR METFORMIN

TABLE 3. ADVERSE EVENTS.

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